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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA LP and ASTRAZENECA AB, Plaintiffs, v. BREATH LIMITED, Defendant.	Consolidated Civil Action No. 08 CV 1512 (RMB)(AMD)
ASTRAZENECA LP and ASTRAZENECA AB, Plaintiffs, v. APOTEX, INC. and APOTEX CORP., Defendants.	

DECLARATION OF MICHAEL S. BURLING, ESQ.

I, Michael S. Burling, hereby declare as follows:

1. I am a member of the bar of the State of New York and am admitted *pro hac vice* to this Court for the limited purpose of appearing in this action. I am an associate at the law firm of Ropes & Gray LLP, 1211 Avenue of the Americas, New York, NY 10036, which represents AstraZeneca LP and AstraZeneca AB (collectively, "AstraZeneca") in the above-captioned action.

2. I submit this declaration in support of AstraZeneca's Memorandum in Opposition to Apotex's Motion to Compel the Production of Communications With In-House Counsel in Sweden (D.I. 211).

3. Attached as Exhibit 1 is a true and correct copy of AstraZeneca's April 19, 2010 letter to the Court in the above-captioned matter (D.I. 182).

4. Attached as Exhibit 2 is a true and correct copy of a translation from Swedish into English of an excerpt from New Legal Archive, 1986, on pages 398 through 402.

5. Attached as Exhibit 3 is a true and correct copy of a certified translation from Swedish into English of the order of the Göta Court of Appeal in the case of Aquatuve i Boxholm AB v. Nya Boxholm Produktion Aktiebolag, issued on June 18, 1996.

6. Attached as Exhibit 4 is a true and correct copy of selected pages from the transcript of the April 29, 2010 status conference with the Court in the above-captioned action.

7. Attached as Exhibit 5 is a true and correct copy of United States Patent No. 7,524,834.

8. Attached as Exhibit 6 is a true and correct copy of selected pages of the Manual Patent Examining Procedure, § 1801 "Basic Patent Cooperation Treaty (PCT) Principles," available at http://www.uspto.gov/web/offices/pac/mpep/documents/1800_1801.htm#sect1801.

9. Attached as Exhibit 7 is a true and correct copy of selected pages of the Manual Patent Examining Procedure, § 1893.03(c) "The Priority Date, Priority Claim, and Priority Papers for a U.S. National Stage Application," available at http://www.uspto.gov/web/offices/pac/mpep/documents/1800_1893_03_c.htm#sect1893.03c.

10. Attached as Exhibit 8 is a true and correct copy of selected pages of the Manual Patent Examining Procedure, § 201.13 "Right of Priority of Foreign Application -- 200 Types, Cross-Noting, and Status of Application" available at http://www.uspto.gov/web/offices/pac/mpep/documents/0200_201_13.htm.

11. Attached as Exhibit 9 is a true and correct copy of selected pages of the Manual Patent Examining Procedure, § 1.55 "Claim for foreign priority. -- Appendix R Patent Rules," available at http://www.uspto.gov/web/offices/pac/mpep/documents/appxr_1_55.htm.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this 30th day of August, 2010 in New York, New York.

Michael S. Burling, Esq.

Exhibit 1

McCARTER &ENGLISH
ATTORNEYS AT LAW

April 19, 2010

VIA ECF

Hon. Ann Marie Donio, U.S.M.J.
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Re: ***AstraZeneca v. Apotex and AstraZeneca v. Breath***
Consolidated Civil Action No. 08 CV 01512 (RMB)(AMD)

Dear Judge Donio:

We write on behalf of plaintiffs AstraZeneca AB and AstraZeneca LP (collectively, "AstraZeneca") to review the state of fact discovery in advance of the April 29 status conference, and to respond to the issues raised by defendants Apotex, Inc. and Apotex Corp. (collectively, "Apotex") in their April 7, 2010 letter. (D.I. 147.) The issues that Apotex raised the afternoon before the previously-scheduled April 8 discovery conference with the Court are entirely without merit. Apotex ignores the facts, including the fact that its discovery requests were untimely. Apotex likewise ignores the law, including American case law establishing that U.S. privilege applies to AstraZeneca's withheld documents, and Swedish law, which if applicable, similarly defeats Apotex's request for production.

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Status of Fact Discovery

Fact discovery has now closed. All depositions, including those of third parties for which notices were issued, have been taken. Until Apotex's last-minute letter, the only matters pending before the Court were: (1) AstraZeneca's motion to compel Apotex to produce documents subject to its waiver of attorney-client privilege (D.I. 109); and (2) AstraZeneca's request that Apotex reimburse AstraZeneca for costs incurred as a result of Apotex's failure to meet discovery deadlines.[1] (D.I. 141.) With respect to the first of those issues, on April 7, AstraZeneca took the deposition of Bernice Tao – the witness through whom Apotex

[1] A third issue has recently arisen. During the April 1, 2010 deposition of Wan Jiang, Apotex's Rule 30(b)(6) corporate witness, Dr. Jiang described additional relevant documents which were not produced to AstraZeneca. At the deposition, AstraZeneca requested production, and has since sent two reminders. Yet, apparently, Apotex is still searching for these documents.

initially waived the privilege during the preliminary injunction hearing. Despite that waiver (and Apotex's repeated reliance on Ms. Tao's disclosure of advice that Apotex received from counsel), Apotex repeatedly instructed Ms. Tao not to answer questions directed to the same subject matter to which she previously testified. These instructions, in effect, rendered Ms. Tao's deposition a nullity.

Further, claim construction briefing closed at the end of last week, when the parties filed responsive *Markman* papers. Opening expert reports are currently scheduled to be exchanged on May 14.[2]

After more than a year of litigation, and the production of more than seven hundred thousand pages of responsive documents by AstraZeneca, it appeared last week as if this case might finally move forward to expert discovery. Then, remarkably, on the eve of the Court's scheduled April 8 status teleconference, Apotex filed a last-minute letter requesting that the Court delve back into fact discovery because, in Apotex's artful phrasing in the passive voice, "various issues have arisen" concerning AstraZeneca's discovery objections and privilege claims. (D.I. 147 at 1.) These new "issues" are mere gamesmanship. Apotex's letter, which includes 23 exhibits and more than 300 pages, misstates the facts and serves only to highlight Apotex's negligence in failing to pursue timely discovery.[3]

AstraZeneca served its initial discovery requests on Apotex on June 30, 2009. In contrast, Apotex waited to serve its ***first*** sets of document requests and interrogatories on AstraZeneca until January 8, 2010 – ***more than seven months*** after fact discovery commenced. Apotex's discovery requests demanded responses and production to be provided only days before the then-scheduled February 19 close of fact discovery, and after most of the depositions of AstraZeneca witnesses.

By the time that Apotex decided to engage in substantive discovery, AstraZeneca had been diligently searching for and producing documents in response to Breath's timely requests for ***more than seven months***. Notwithstanding the fact that Apotex made no document requests to AstraZeneca, beginning in July 2009, AstraZeneca produced to Apotex copies of documents that it produced to Breath. Indeed, in that month alone, AstraZeneca produced to Apotex about half a million

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[2] On April 15, 2010, the Court entered the parties' stipulated amendment to the case Scheduling Order, extending the expert discovery schedule by two weeks. (D.I. 169.)

[3] AstraZeneca was surprised by Apotex's letter to the Court. AstraZeneca had understood that Apotex's requests were no longer at issue, particularly in view of the fact that Apotex did request any conference with AstraZeneca to address its requests. *See* L.R. 37(a)(1).

pages that were produced in the previous *Ivax* case. AstraZeneca supplemented that production to both Breath and Apotex throughout 2009, in response to Breath's discovery requests. In doing so, AstraZeneca undertook significant expense and effort (including multiple overseas trips by counsel) to search for, collect, process and produce its documents well before the end of fact discovery in February 2010.

Throughout the entirety of 2009, while Apotex was reviewing AstraZeneca's documents, Apotex ***never*** once questioned, let alone complained about any alleged deficiencies in AstraZeneca's production. And, during extensive fact depositions conducted in January and February 2010, Apotex ***never*** once raised any of the alleged discovery deficiencies identified in its letter to the Court last week.

Apotex's delinquencies in this regard are no different from its delinquencies in providing discovery to AstraZeneca. As the Court will recall, Apotex confessed in December 2009 that it had neither collected nor produced any electronic documents in response to AstraZeneca's document requests. This necessitated two fact discovery extensions, and generated significant costs for AstraZeneca's counsel, who had to reschedule other client matters and cancel deposition and travel plans. These issues were detailed in AstraZeneca's March 10, 2010 letter to the Court. (D.I. 137.)

Only litigation tactics can explain why Apotex spent the better part of a year waiting to provide discovery, and, now, to also seek discovery of allegedly "highly relevant" information, and the intervention of the Court. Apotex's tactics not only threaten to significantly delay the case, but, as explained below, they lack substantive merit.

AstraZeneca's Discovery Objections Concerning Labeling Are Proper

AstraZeneca contends that Apotex's proposed generic version of PULMICORT RESPULES®, a nebulizable budesonide inhalation suspension ("BIS") product, will infringe the claims of AstraZeneca's patents-in-suit. Such patents include U.S. Patent Nos. 6,598,603 (the "'603 patent") and 6,899,099 (the "'099 patent"), which are directed to kits and methods for treating respiratory diseases by the administration of nebulized budesonide compositions in a continuing regimen of "not more than once per day." Apotex portrays Interrogatory No. 11 and Document Request Nos. 14-16 as "directly tailored" and "narrowly relevant" to a "central issue" that "goes to the very heart of this case." (D.I. 148 at 14-15; D.I. 150 at 13-15.) But Apotex's explanation of these allegedly vital requests, which took seven months to serve, is wrong.

1. Apotex's Interrogatory No. 11

Apotex Interrogatory No. 11 requests

> [f]or each country in which a nebulizable BIS [budesonide inhalation suspension] Product has been sold by or on behalf of Plaintiffs, identify (i) whether any instructions to titrate down to the lowest effective dose accompanied any sale of that product prior to December 31, 1997, and (ii) the specific language of those instructions. (D.I. 147 at 2.)

As an initial matter, this interrogatory, like Apotex's other discovery requests, seeks information that Apotex has refused to produce to AstraZeneca, *i.e.,* discovery concerning products other than those specifically at issue in this litigation. For example, in response to AstraZeneca's First Set of Requests for the Production of Documents and Things, Apotex repeatedly objected to discovery concerning its BIS products by stating that "Apotex further objects to this request to the extent that it is not limited to the product described in Apotex's ANDA No. 78-202."[4] Likewise, in its responses to AstraZeneca's First Set of Requests for Admission, Apotex even claimed that the term "Apotex's BIS," referring to Apotex's budesonide inhalation suspension, was "vague and indefinite."[5] Thus, Apotex refused to produce any documents other than those relating to the specific United States BIS product at issue in this case. For both AstraZeneca and Apotex, that product is AstraZeneca's PULMICORT RESPULES®. Apotex has sought and obtained FDA approval to market a generic version of PULMICORT RESPULES®. There are ***no*** foreign products involved in this case at all. Apotex's unilateral demand of foreign discovery should be denied.

Beyond that, Apotex dismisses AstraZeneca's substantive response to this interrogatory as "providing no information." (D.I. 147 at 2.) As even a cursory glance at AstraZeneca's response shows, however, AstraZeneca confirmed that it "did not sell a nebulized BIS product in the United States prior to December 31, 1997 that was accompanied by an instruction to titrate down to the lowest effective dose." (D.I. 148 at 15.) And, as AstraZeneca has explained to Apotex in correspondence (including citations to AstraZeneca's FDA submissions),

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[4] Ex. A, Apotex's Objections And Responses to AstraZeneca's First Set of Requests for the Production of Documents and Things (Nos. 1-61), dated August 17, 2009, at 7-25, 32, 36 and 44.

[5] Ex. B, Apotex's Objections and Responses to AstraZeneca's First Set of Requests for Admission to Apotex (Nos. 1-88), dated August 17, 2009, at 4-5.

AstraZeneca BIS products sold overseas prior to December 31, 1997 were all approved for ***twice-daily*** administration. (D.I. 149 at 2.) These products were unaccompanied by instructions indicating, whether explicitly or implicitly, that such products could be administered to a patient once daily. (D.I. 148 at 14.) There is simply no basis for assuming that the instructions for foreign BIS products are relevant to the asserted claims of the patents-in-suit. And, it is inconceivable that anyone before December 31, 1997 would have understood such language as relevant to once-daily administration.

Moreover, even if the information that Apotex now seeks is relevant to the case, its marginal relevance is far outweighed by the burden to AstraZeneca of having to go back and search AstraZeneca's files for responsive documents, and then collect, process and produce such documents. This burden is significant. As AstraZeneca explained to Apotex, by December 31, 1997, its BIS products had been sold in over ***thirty*** foreign countries. (D.I. 149 at 2.) As AstraZeneca also explained, AstraZeneca does not archive such dated product labels in a centralized database. (D.I. 152-1 at 3.) Apotex's request would, therefore, require AstraZeneca to search for information from dozens of countries for documents that may be decades old. Apotex's demands are excessively burdensome. *See Pub. Serv. Enter. Group Inc. v. Phila. Elec. Co.*, 30 F.R.D. 543, 551-52 (D.N.J. 1990). Moreover, Apotex's arguments suggest that it believes these labels to be public prior art. If this is so, then it makes little sense to require AstraZeneca to undertake Herculean efforts to find these documents.[6] Instead, Apotex should have collected these documents from public sources, rather than unfairly shifting the collection burden to AstraZeneca.

2. Document Request Nos. 14-16

Apotex's Document Request Nos. 14-16 seek the first government-approved label and/or package insert for, and the first or any revised versions of a label and/or package insert accompanying,

> [the] products known as Pulmicort, Pulmicort Respules, Pulmicort Turbuhaler, Pulmicort pMDI, Rhinocort, Rhinocort Aqua, Rhinocort Turbohaler, Rhinocort pMDI, Spirocort, Spirocort Aqua, Spirocort Turbohaler, Spirocort Nebu, Budamax, Pulmicort Nebuamp, Pulmicort Turbuhaler, Rhinocort Turbuhaler, Rhinosol, Aircort, Nebuhaler, and any product having the same formulations as any of the products

[6] This is especially true given that AstraZeneca would have produced such documents found in its files during previous searches.

> bearing these trade names, in each country for which the product has been sold. (D.I. 150 at 13-15.)

This exhaustive litany is inconsistent with Apotex's claim that these Document Requests are focused on "very specific" documents. (D.I. 147 at 3.) In fact, Apotex seeks documents on over ***nineteen*** budesonide products sold by AstraZeneca all over the world. For the same reasons discussed above in connection with Apotex's Interrogatory No. 11, there is no basis to assume that these labels and/or package inserts are relevant to the claims of the patent-in-suit. Contrary to the suggestion in Apotex's letter to the Court, Apotex has ***never*** explained to AstraZeneca why these requests are relevant. Instead, Apotex has ignored AstraZeneca's substantive objections, and made only conclusory assertions that the requested labels are "relevant to at least Apotex's invalidity contentions." (D.I. 152 at 3.) But that cannot be. This request is not limited to seeking documents before the filing date of the '603 and '099 patents. Apotex's gloss is plainly insufficient to warrant the burdensome production that Apotex seeks.

Moreover, as explained above, Apotex's Document Requests contradict positions that Apotex took throughout fact discovery, when it argued that products other than its specific generic version of PULMICORT RESPULES® was irrelevant to this case. For example, in response to AstraZeneca's First Set Of Document Requests, Apotex objected to "AstraZeneca's definition of 'Budesonide inhalation product' as vague, ambiguous, overly broad, and unduly burdensome to the extent that it includes any 'product developed, under development, considered for development, marketed or sold by Apotex, or anyone else, that includes budesonide as an active ingredient and is administered by inhalation.'"[7] Apotex should not now be permitted to change its position on the relevance of other products to launch an evidentiary fishing expedition.

AstraZeneca's Discovery Objections Concerning Prior Product Sales Are Valid

1. Interrogatory No. 16

Apotex's Interrogatory No. 16 requests:

> For each country in which a product containing budesonide has been sold by or on behalf of Plaintiffs prior to November 14, 1997, identify the date on which a sterile version of that product was first sold. (D.I. 148 at 17.)

[7] Ex. A at 5.

In a March 9, 2010 letter to counsel for AstraZeneca, Apotex justified Interrogatory No. 16 with puzzling logic: "[s]ales of such products ***implies*** [*sic*, imply] the existence of publications regarding the same, and is [*sic*, are] therefore relevant to the validity of [United States Patent 7,524,834] (the "'834 patent")." (D.I. 148-1 at 2.) This is nonsense. As Apotex knows full well, foreign sales are irrelevant to validity under the patent statute, which limits prior art to inventions "patented or described in a printed publication in this or a foreign country ***or in public use or on sale in this country***, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b)[8]. Apotex's interrogatory is not directed to publications – real or implied – but rather to sales information. Even now, Apotex insists to the Court that AstraZeneca's overseas sales "are directly relevant to the invalidity of Plaintiffs' sterilization patent." (D.I. 147 at 4.) With respect to U.S. sales, AstraZeneca has already confirmed that "it has not sold any sterile inhalation product prior to November 14, 1997." (D.I. 149 at 3.) Further, the only sterile budesonide product sold outside the U.S. prior to that date was a cream for topical administration (Preferid®). As discussed below in connection with Document Request Nos. 43 and 44, discovery concerning that product is both irrelevant and would be incredibly burdensome to locate, if it could be located at all. And, there is no basis to assume the existence of any of the foreign publications sought, or, if they do exist, that they would be relevant as prior art publications to the claims at issue in this case.

In addition to not being "directly relevant", Apotex's Interrogatory No. 16 is not "narrowly tailored." (D.I. 148 at 17.) It requests foreign sales information on "***any*** sterile" version of "***any*** product containing budesonide", far beyond the products at issue that Apotex has previously asserted to be the only products relevant in this case. AstraZeneca does not record the dated information sought by this request in any file or database. Thus, the burden of collecting this information would be significant; it would require AstraZeneca to laboriously search files in dozens of countries at significant expense. This burden is simply not justified by Apotex's untimely and irrelevant interrogatory.

2. Document Request Nos. 43 and 44

These Document Requests request all documents and things concerning the "sterilization requirements for the manufacture and/or sale" or the "labeling and package insert information" for "Preferid®, including the Preferid® product marketed in Scandinavian countries." (D.I. 151 at 30-31.) Apotex has characterized these Document Requests as "relevant to at least Apotex's invalidity contentions." (D.I.

[8] Throughout this letter, emphasis in quotations has been added unless otherwise stated.

152 at 4.) However, Apotex's rote recitation of relevance falls far short of a clear, legally valid explanation of ***how*** these products affect ***Apotex's invalidity contentions in this case***. Tellingly, despite having responsive information concerning Preferid®, Apotex does not mention that product in its contentions at all. And, it cannot be sufficient explanation that Apotex's Document Requests merely "relate[] to a sterile budesonide product" (D.I. 147 at 5.) Preferid® was a topical budesonide cream sold by AstraZeneca outside the United States, briefly and many years ago. Although for a limited time it was identified as "sterile according to Ph.Eur.", information concerning this product, including its method of manufacture and labeling information, has no bearing on this litigation. Preferid® was never marketed in the United States. Moreover, its identification as a sterile product was derived from European standards, not from the criteria of sterility provided in the United States Pharmacopeia, as set forth in the '834 patent claims. Collecting information for these Document Requests would thus require AstraZeneca to conduct burdensome searches in foreign countries looking for documents from many years ago, if those documents even exist at all.

In view of the above, AstraZeneca respectfully requests that the Court dismiss Apotex's motion to compel production of the discovery identified in Apotex's April 7, 2010 letter.

* * *

AstraZeneca's Attorney-Client Privilege Claims Are Justified

On January 15, 2010, counsel for AstraZeneca requested Apotex to return an inadvertently produced document shielded by the attorney-client privilege. (D.I. 152-2.) This document reflects a privileged and confidential communication to James Peel, a former AstraZeneca in-house patent counsel in Sweden, from the AstraZeneca inventors of the '834 patent.[9] Upon receipt of AstraZeneca's letter,

[9] Apotex's arguments impugning AstraZeneca's legitimate claims of attorney-client privilege exemplify a strategy of delay. These issues could easily have been raised ***months*** ago if Apotex had not dragged its feet during discovery. **Indeed, as early as last November, counsel for AstraZeneca proposed a December 2009 exchange of privilege logs with Apotex and Breath**. Ex. C, November 17, 2009 letter from Derek Kato, Esq. to Amy Brody, Esq. and David Aldrich, Esq. Counsel for AstraZeneca made additional inquiries in December 2009 and February 2009 about exchanging privilege logs. In view of this delay, and the general obfuscation in which Apotex has engaged during fact discovery, Apotex's attempt to raise last-minute privilege issues should be denied as untimely.

Apotex was required by the plain language of the Discovery Confidentiality Order to "promptly. . . return" the document. (D.I. 90 at 10.) Yet Apotex held the document back for ***more than two months***. Now, Apotex asks this Court to compel the production of ***more than 90*** AstraZeneca documents.[10] As explained below, it is clear from even a cursory review of the law that Apotex's analysis of the privilege issue is incorrect.

1. U.S. Privilege Law Applies To The Privileged Communications

Apotex suggests that Swedish law controls in assessing whether the AstraZeneca documents identified in its April 7, 2010 letter are privileged. This is wrong. In fact, these documents are properly evaluated under ***U.S.*** privilege law which without doubt protects the documents at issue.

District Courts, including one District Court in this Circuit, have found that privileged communications "touching base" with the United States are properly governed by U.S. discovery rules. *See, e.g.*, *Astra Aktiebolog v. Andrx Pharms.*, 208 F.R.D. 92, 98 (S.D.N.Y. 2002); *Tulip Computers Int'l B.V., v. Dell Computer Corp.*, 210 F.R.D. 100, 104 (D. Del. 2002); *Willemijn Houdstermaatschaapij BV v. Apollo Computer*, 707 F. Supp. 1429, 1445 (D. Del. 1989); *Golden Trade S.r.L. v. Lee Apparel Co.*, 143 F.R.D. 514, 520 (S.D.N.Y. 1992) (listing cases). Federal Courts will grant deference to foreign statutes in certain circumstances, respecting principles of international comity, so long as that foreign law is not contrary to the public policy of the American forum. *See Odone v. Croda Int'l*, 950 F. Supp. 10, 12 (D.D.C. 1997).

Here, the privileged documents identified by Apotex all "touch base" with the United States. More than half of these documents relate to the preparation and prosecution of a United States patent application, from which two of the U.S. patents-in-suit claim priority.[11] For these documents, AstraZeneca's privilege log clearly identifies an attorney from AstraZeneca's U.S. counsel (Fish & Richardson) as either a sender or recipient. Such communications between patent counsel and client are clearly privileged. *In re Spalding Sports Worldwide, Inc*., 203 F.3d 800, 805 (Fed. Cir. 2000); *Bristol-Myers Co.v. Sigma Chem. Co.*, 7 U.S.P.Q. 2d 1574, 1576 (D. Del. 1988). Courts have found analogous communications between foreign

[10] Apotex identifies the withheld documents at issue by their entry number on AstraZeneca's privilege log. (D.I. 147 at 8, n. 36.)

[11] Doc. Nos. 34-38, 41-43, 50-56, 59-72, 90-97, 99-101, 113-114, 121, 123-126, 156-157, 182, 183, 185, and 186.

in-house counsel and outside American counsel to "touch base" with the United States, and thus to fall within the purview of American privilege rules. *See, e.g.*, *Astra Aktiebolog*, 208 F.R.D. at 99.

The remaining privileged documents identified by Apotex involve either the Swedish priority application for one of the U.S. patents-in-suit,[12] or the Patent Cooperation Treaty ("PCT") application through which that Swedish application was granted priority in the U.S.[13] The PCT provides, among other things, procedures by which applicants may seek patent protection for an invention in multiple countries by filing a single "international" patent application that designates the countries in which protection is sought. There are over 140 signatory countries, including the U.S. It should not be surprising that multinational companies like AstraZeneca routinely seek overseas (particularly in the U.S.) patent protection by filing PCT applications after an initial foreign filing is made.

Courts have found that communications concerning foreign priority applications for U.S. patents sufficiently "touch base" with the United States. These communications are therefore governed by U.S. privilege law, not Swedish law. *See Odone*, 950 F. Supp. at 13-14; *Astra Aktiebolog*, 208 F.R.D. at 99. And, such communications would be privileged regardless of whether the communication at issue involves an attorney or a patent agent because patent agents (foreign or U.S.) perform lawyer-like functions in connection with patent issues. *See Venitron Med. Prods. Inc. v. Baxter Labs., Inc.*, 186 U.S.P.Q. 324, 325-26 (D.N.J. 1975); *Golden Trade S.r.L*,143 F.R.D. at 519.

Even if this Court were to hold that AstraZeneca's privileged documents did not "touch base" with the U.S., American privilege law should still apply. This was the outcome in the *Astra Aktiebolog* case, in which the Southern District of New York examined communications involving, in part, in-house counsel and outside Korean counsel. *Astra Aktiebolog*, 208 F.R.D. at 99. The Court first considered Korean law, noting that no statutory attorney-client privilege existed in Korea. *Id.* at 100-01. The Court then noted that none of the documents at issue in the case would be discoverable in a Korean civil proceeding. *Id.* at 101. In light of these circumstances, the Court declined to find

> that the absence of Korean attorney-client privilege and work product provisions requires this court to order the wholesale

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12 Doc Nos. 6, 8-13, 19-26, 30-32, 118, 127, 128, and 130-132.

13 Doc. Nos. 129, 149-153, 173-176, 187, 194, and 248.

> production of all of the Korean documents in their entirety. To do so would violate principles of comity and would offend the public policy of this forum.

Id. at 102.

The Court continued:

> The fact is that vastly different discovery practices, which permit only minimal discovery, are applicable to civil suits conducted in Korea. Indeed, none of the documents at issue here would be discoverable in a Korean civil suit. Under these circumstances, where virtually no disclosure is contemplated, it is hardly surprising that Korea has not developed a substantive law relating to attorney-client privilege and work product that is co-extensive with our own law. . . . ***[T]o apply Korean privilege law, or the lack thereof, in a vacuum – without taking account of the very limited discovery provided in Korean civil cases – would offend the very principles of comity that choice-of-law rules were intended to protect.***
>
> Further, ordering discovery without any protection also offends the public policy of this forum, which promotes full discovery but, at the same time, prevents disclosure of privileged documents. ***If the court were to rule without taking Korea's discovery practices into account, the court would be required to order complete disclosure of all of the Korean documents, many of which would be protected under either the attorney-client privilege or work product doctrine as applied in this jurisdiction.***

Id. (citation omitted.)

The Court concluded that the "application of foreign privilege law . . . would require disclosure of many documents (1) that are protected from disclosure under American law and (2) that would not be discoverable under Korean law." *Id.* Faced with this outcome, the Court instead applied U.S. privilege law, even though the documents at issue did not "touch base" with the U.S.

Thus, even if the Court in this case were to find that AstraZeneca's privileged documents failed to "touch base" with the U.S., and even if there is no statutory

privilege protection in Sweden for in-house counsel, this Court should properly apply U.S. privilege law to those documents to preserve principles of public policy.

2. Apotex Mischaracterizes The Swedish Law Concerning Privilege

Apotex's discussions concerning Swedish privilege law are irrelevant and incomplete. Apotex's letter summarily dismisses as "inapposite" two cases cited in earlier correspondence by AstraZeneca, in which courts recognized a Swedish affidavit on the applicability of attorney-client privilege to in-house attorneys in Sweden as persuasive evidence. *See Santrade Ltd. v. Gen. Elec. Co.*, 150 F.R.D. 539 (E.D.N.C. 1993); *Saxholm AS v. Dynal, Inc.*, 164 F.R.D. 331 (E.D.N.Y. 1996). Both of these cases are consistent with the one case Apotex cited in its response letter to AstraZeneca. *In re Rivastigmine Patent Litig.*, 237 F.R.D. 69 (S.D.N.Y. 2006). Observing that the assumptions and ultimate rulings in *Santrade* may have been appropriate based on the evidence before that tribunal, the *Rivastigmine* Court declined to find privilege only because no evidence of Swedish law had been submitted to it in that case. *In re Rivastigmine,* 237 F.R.D. at 100. Thus, *Santrade*, *Saxholm* and *Rivastigmine* are in accord: declarations are persuasive evidence of Swedish law that courts may consider in their privilege evaluations. Apotex has submitted no such declaration.

At this late stage, with fact discovery over, *Markman* briefing completed and expert discovery about to begin, AstraZeneca respectfully submits that this case should not get sidetracked into collateral briefing over details of Swedish law. However, to the extent that this Court finds that the disputed AstraZeneca documents do not "touch base" with the U.S., AstraZeneca has submitted the Declaration of Peter Sande (the "Sande declaration") as authoritative evidence on matters of Swedish civil and evidentiary law.[14]

As explained in the Sande declaration, whether or not Swedish statutory privilege extends to in-house counsel is not determinative. Sweden is a civil law country in which, absent extraordinary circumstances, the law forbids forced disclosure of any communications or documents reflecting legal advice, or requests for legal advice, between members of an in-house legal department and the parent company.[15] No such circumstances are present in this case. As a result, the documents and information identified by Apotex in its April 7, 2010 letter ***could not be compelled in Sweden*** under that country's laws.[16] And, even though the Swedish prohibitions on forced disclosure are procedural in nature, they are, as discussed

[14] Ex. D, April 16, 2010 Declaration of Peter Sande.
[15] Ex. D at ¶ 15.
[16] Ex. D at ¶ 18.

previously, relevant for U.S. courts evaluating assertions of privilege. *See Astra Aktiebolog*, 208 F.R.D. at 99-102.

In view of the above, AstraZeneca respectfully requests that the Court deny Apotex's motion to compel the privileged documents identified in Apotex's April 7, 2010 letter.

We look forward to addressing these issues with Your Honor at the status conference on April 29, 2010.

Respectfully submitted,

s/John E. Flaherty

John E. Flaherty

cc: Counsel of Record (via ECF)

Exhibit 2

Åsa Schoening, Translator & Interpreter
44 Rivers Edge Drive
Little Silver, NJ 07739

August 20, 2010

I, Åsa Schoening, hereby certify that to the best of my knowledge, the translation from Swedish into English of an excerpt from New Legal Archive, 1986, on pages 398 through 402, is both accurate and complete.

Åsa Schoening

[label:]

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1986

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Issue, in case regarding damages due to infringement of copyright, regarding the obligation of Defendant to disclose certain sales information concerning dates, volumes and prices during the course of an investigation regarding the extent of the damage. Trade secret? Comparison of Chapter 38, § 2 with Chapter 36, § 6 of the Legal Code.

(Cf. 1953 p. 19)

After filing suit against Aktiebolaget Svenska Cykelställfabriken (Cykelställfabriken) before *Motala District Court*, Aktiebolaget Hags Mekaniska (Hags) sought damages by Cykelställfabriken, claiming that the same had infringed Hags' copyright by manufacturing and marketing copies of Hags' play unit "Småland" under the names "Pergola" and "Östergyllen."

In order to determine the extent of the demanded damages, Hags claimed that Cykelställfabriken be ordered to submit a written, accountant-certified compilation of the factory's accounting records for the period of 1 Jan. 1982 – 2 Sep. 1983 of the number of sold whole units of "Pergola" and "Östergyllen," indicating the sales price and date of sale. Cykelställfabriken opposed the claim, claiming e.g. that the information amounted to trade secrets, the disclosure of which would seriously harm Cykelställfabriken.

Cykelställfabriken claimed that before a decision were handed down in the matter regarding the directive to produce documents, the District Court should examine the infringement matter through an intermediate judgment. Hags opposed the claim for an intermediate judgment.

The *District Court* (Assistant Judge *Karlsson*) made public its order on 21 May 1985, wherein the claim for intermediate judgment was denied and Cykelställfabriken was ordered to submit to the District Court no later than 1 July 1985 the compilation demanded by Hags.

Cykelställfabriken appealed to the *Göta Court of Appeal* and claimed that the Court of Appeal must sanction the claim for an intermediate judgment and rescind the order in favor of the directive to produce documents.

The Court of Appeal (Judges of Appeal *Löwendahl, Åkesson*, Reporter of the Case, and *Rundgren*) reasoned in the final order of 28 June 1985 e.g.: *Motions before the Appellate Court, etc.* – – – In addition to that which has been argued before the Appellate Court, Cykelställfabriken has

stated e.g. the following: To compile the information referred to in the directive to produce documents has been estimated to take about five months. In view hereof, it will not be possible to hold the main proceedings on 21-23 October 1985 as scheduled. Thus, the directive to produce documents results in an unnecessary delay of the case. An intermediate judgment should therefore be issued in the infringement matter. – The "Pergola" and "Östergyllen" construction systems include other combinations than those claimed by Hags to infringe their copyright. The directive to produce documents should therefore at the very least be limited to the systems covered by the process framework and that are encompassed by the motion to compel production of documents, i.e. the products/combinations depicted on pages 1b, 2b, and 4b in App. 3 of the summons. There is seemingly no legal basis for ordering the party in support of Chapter 38, § 2 of the Legal Code to produce an accountant-certified compilation.

Hags has consented to the directive to produce documents being given the content indicated by Cykelställfabriken, but has otherwise opposed the appeals.

Order by the Court of Appeal. The Court of Appeal amends the order by the District Court only so that the compilation in accordance with the directive to produce documents should relate to the products/combinations depicted on pages 1b, 2b, and 4b in App. 3 of Hags' summons.

Cykelställfabriken lodged an appeal (representative Attorney Anders Hessle) and claimed that the Superior Court must, by vacating the order by the Court of Appeal, reject Hags' motion to compel production of documents.

Hags (representative Attorney Kaj Sandart) opposed the appeals.

The case was decided subsequent to the presentation of a report on the case.

The presenter, Judge Referee *Olsson*, requested in his report that the Superior Court must issue the following order: *Reasoning.* The information requested by Hags should be deemed necessary for the investigation of the presented claims for damages. According to their own statement, Cykelställfabriken possesses order acknowledgements and invoices, the supporting documentation of which provides the requested information. These documents can therefore be assumed to be of importance as evidence.

The mentioned information relates to the sale by Cykelställfabriken of certain embodiments of freestanding outdoor rooms as well as play and climbing equipment consisting of construction elements built separately that may be combined. It has been stated in the case that Hags and Cykelställfabriken are main competitors on the Swedish market in terms of such products. In view of further information provided regarding the market and competitive conditions within the industry and other circumstances, primarily that of Cykelställfabriken being a smaller company, the information requested by Hags must be deemed to constitute Cykelställfabriken's trade secret. According to Chapter 38, § 2 of the Legal Code, compared to Chapter 36, § 6 of the same Code, there is no obligation to provide at trial a document containing such information, unless there is particular reason for doing so. In the event of such an examination, the Court must weigh against each other the different interests that are at issue. If Plaintiff in a case regarding damages due to infringement of copyright claims that Defendant should be ordered to produce information on its sale of products alleged to infringe, the sanctioning of the claim should require that the Court has found at least some likelihood of Defendant having infringed the copyright. It is a given that the application of even such a limited evidentiary requirement during the preparatory proceedings of the case may be precarious and therefore calls

for the use of caution in the examination. This is true not in the least if, as in the present case, it is disputed not only whether Defendant has infringed but also whether Plaintiff's products enjoy any copyright protection at all.

The issue of whether there exists any particular reason with regards to the directive to produce documents should also be evaluated in view of the ability of the parties in accordance with the regulations in Chapter 17, § 5, Paragraph 2 of the Legal Code to request an intermediate judgment on the infringement suit and Defendant's obligation to pay damages, whereas the issue of the extent of the damages will be examined later, unless the Plaintiff's petition is rejected in terms of the detached issue, or unless the parties agree on a settlement regarding the amount of damages. In the event that Defendant is found liable for damages, one could obviously have no reservations about ordering the same to present such information – if Defendant does not freely provide the necessary information for determining how to calculate the damages.

According to section just mentioned above, one condition for dividing the case through an intermediate judgment is that it would be suitable with regards to the investigation to separate the different issues of dispute. Similarly, it is true that an intermediate judgment may be issued against the opposition by one party only if there are particular reasons.

In this case Hags has opposed the claim by Cykelställfabriken for intermediate judgment on Hags' suit regarding the infringement of the company's copyright. A judgment regarding this issue and as to whether Cykelställfabriken is liable for damages was suitable in view of the investigation. The claim was presented at an early stage of the trial, at which point Cykelställfabriken also indicated that it was prepared, in the event that the company was found to have infringed Hags' copyright, to provide of its own free will the information requested by Hags. Therefore, compared to the present situation, the process of an intermediate judgment cannot be considered to have brought any negative consequences for Hags.

In view of what has been brought forward and what has occurred regarding the infringement issue, one cannot find that arguments have been presented to show an existing reason to presently order Cykelställfabriken to provide a document containing the information requested by Hags. Thus, Hags' claim for such a directive is to be rejected.

Decision by the Supreme Court. Amending the order by the Court of Appeal, the Supreme Court dismisses upon its merits the motion to compel production of documents.

The Supreme Court (Justices of the Supreme Court *Brundin, Erik Nyman, Palm, Rydin,* Reporter of the Case, and *Solerud*) reached the following final order: *Reasoning*. Hags claimed before the District Court for damages to be paid by Cykelställfabriken, claiming that the factory had infringed Hags' copyright. According to Hags, the infringement consisted of Cykelställfabriken producing and marketing copies of Hags' play equipment Småland. Hags has preliminarily estimated the extent of the damage to a total of SEK 1,100,000 plus interest. The amount refers to the following items: SEK 250,000 for the use of the rights, SEK 750,000 for other commercial damage, and SEK 100,000 for loss of goodwill. Hags has reserved the right to increase the requested damages, in the event that the investigation in the case provides a reason to do so. In order to specify the extent of the damages, Hags claimed before the District Court, according to what's been recorded in minutes from preparatory proceedings in the case, that Cykelställfabriken be ordered to demonstrate through certificates the dates, volumes, and prices of the sale of the copies for the period of 1 Jan. 1982 – 2 Sep. 1983.

Cykelställfabriken opposed Hags' petition for damages at the District Court, claiming mainly that Hags' products-in-suit are not copyright-protected and that the factory in any case is not guilty of infringement. Cykelställfabriken also opposed the motion to compel production of documents. In support hereof, Cykelställfabriken has maintained, in addition to what follows from their position vis-à-vis the issue of damages, that the information requested by Hags refers to trade secrets, the disclosure of which may seriously hurt the factory. Cykelställfabriken has also asserted that the requested information is of no importance for calculating the damages, since the Court may apply the general evidentiary rule in Chapter 35, § 5 of the Legal Code.

The case before the Superior Court concerns only the directive to produce documents. The parties have invoked a number of written reports in the case. Thus, Cykelställfabriken has referred to reports by Professor Gunnar Karnell and Docent Marianne Levin, whereas Hags has referred to reports by Professor Ulf Bernitz, former Principal Åke Huldt, and former Administrative Director Eva Insulander.

One condition for anyone to be enjoined to produce a written document in his possession is according to Chapter 38, § 2, Paragraph 1 of the Legal Code that the document can be assumed to be of evidentiary value. The fact that the Court in some circumstances, supported by Chapter 35, § 5 of the Legal Code, may estimate damages that form the object of a dispute does not relieve the party of his obligation to present the investigation that can be produced within reason (see NJA II 1943 p. 449). The latter regulation can therefore not be referred to as a basis for stating that the investigation regarding the extent of damages indicated in Hags' motion to compel production of documents lacks importance as evidence. Instead, in the intended sentence in Chapter 38, § 2, Paragraph 1, the investigation is assumed to be of importance as evidence in the case.

The information requested by Hags regarding the sales by Cykelställfabriken, in particular in consideration of the statements made in the case regarding the competitive circumstances in the industry, must on the whole be deemed to constitute a trade secret of Cykelställfabriken. According to Chapter 38, § 2, Paragraph 2 of the Legal Code, compared to Chapter 36, § 6 of the same Code, there is no obligation at trial to produce a document containing a trade secret, unless there is a particular reason to do so.

In examining whether there is particular reason for Cykelställfabriken to have to reveal its affected trade secret, the issue of how well-founded Hags' allegation of copyright infringement on the part of the factory is of importance, e.g. Relatively strict requirements must be met for the motion to compel production of documents to be sanctioned in this regard – in consideration of the damage that may arise for Cykelställfabriken from handing over the information. The evaluation that can be made now on the basis of the investigation so far does not yield a result in favor of Hags that would indicate the presence of a particular reason to enjoin Cykelställfabriken to reveal its trade secret.

As a result of what has been brought forth, it is not possible at present to grant Hags' motion to compel production of documents.

Decision by the Supreme Court. Amending the order by the Court of Appeal, the Supreme Court dismisses upon its merits Hags' motion to compel production of documents.

The Reporter of the Case, Justice of the Supreme Court *Rydin* added: Cykelställfabriken claimed before the District Court that the copyright and infringement issues be decided upon separately through an intermediate judgment, before any order was made regarding the part concerning the production of documents. Hags opposed this claim and no intermediate judgment was issued. If an intermediate judgment will be issued during the continued prosecution of the damages case and if Cykelställfabriken is found liable to pay damages, the issue of enjoining the factory to disclose the requested information would obviously be in another position than at present. It can be noted that Cykelställfabriken has declared itself prepared to provide the information of its own free will under the above-indicated circumstances. If, on the other hand, an intermediate ruling was to find Cykelställfabriken not liable to pay damages, the issue of producing documents would come to nothing.

The order of the Supreme Court was issued on 18 July 1986 (no. SÖ 417).

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HD:s dom meddelades d 14 juli 1986 (nr DB 22).

Samtidigt med det refererade målet och på samma sätt som detta avgjordes ett likartat mål mellan Bo N och riksåklagaren (nr DB 21).

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Fråga, i mål om skadestånd på grund av intrång i upphovsrätt, om skyldighet för svaranden att för utredning om skadans storlek lämna ut vissa försäljningsuppgifter avseende datum, volym och pris. Yrkeshemlighet? 38 kap 2 § jämförd med 36 kap 6 § RB.

(Jfr 1953 s 19)

Aktiebolaget Hags Mekaniska (Hags) yrkade efter stämning å Aktiebolaget Svenska Cykelställfabriken (Cykelställfabriken) vid *Motala TR* skadestånd av Cykelställfabriken under påstående att denna gjort intrång i Hags' upphovsrätt genom att tillverka och marknadsföra plagiat av Hags' leksystem "Småland" under namnen "Pergola" och "Östergyllen".

För att kunna bestämma storleken av fordrat skadestånd yrkade Hags föreläggande för Cykelställfabriken att inge skriftlig, av revisor styrkt sammanställning av fabrikens redovisningshandlingar för tiden d 1 jan 1982—d 2 sept 1983 över antalet försålda helheter av "Pergola" och "Östergyllen" med angivande av försäljningspris och försäljningsdag. Cykelställfabriken bestred bifall till yrkandet under påstående bl a att uppgifterna utgjorde yrkeshemligheter, vars utlämnande allvarligt skulle skada Cykelställfabriken.

Cykelställfabriken yrkade att TR:n, innan beslut i frågan om editionsföreläggande meddelades, skulle pröva intrångsfrågan genom mellandom. Hags motsatte sig bifall till yrkandet om mellandom.

TR:n (tingsfiskalen *Karlsson*) meddelade d 21 maj 1985 beslut, vari yrkandet om mellandom lämnades utan bifall och Cykelställfabriken förelades att senast d 1 juli 1985 till TR:n inge den av Hags yrkade sammanställningen.

Cykelställfabriken anförde besvär i *Göta HovR* och yrkade att HovR:n måtte bifalla yrkandet om mellandom samt undanröja beslutet om editionsföreläggande.

HovR:n (hovrättsråden *Löwendahl*, *Åkesson*, referent, och *Rundgren*) anförde i slutligt beslut d 28 juni 1985 bl a: *Yrkanden i HovR:n m m.* — — — Utöver vad som anförts vid TR:n har Cykelställfabriken gjort gällande bl a följande: Att sammanställa de uppgifter som editionsföreläggandet avser beräknas ta omkring fem månader. På grund härav kan huvudförhandling inte, såsom planerats, äga rum d 21—23 okt 1985. Editionsföreläggandet medför således att målet onödigt uppehålles. Därför bör mellandom ges i intrångsfrågan. — I byggsystemen "Pergola" och "Östergyllen" ingår andra kombinationer än de som Hags påstår utgör intrång i deras upphovsrätt. Editionsföreläggandet bör därför i vart fall inskränkas till de system som ryms inom processramen och som omfattas av yrkandet om editionsföreläggande nämligen de produkter/kombinationer som är avbildade på sidorna 1b, 2b och 4b i bil 3 till stämningsansökan. Laga grund torde saknas att förelägga part med stöd av 38 kap 2§ RB att framställa en av revisor bestyrkt sammanställning.

Hags har medgivit att editionsföreläggandet ges det innehåll som Cykelställfabriken angivit men i övrigt bestritt bifall till besvären.

HovR:ns beslut. HovR:n ändrar TR:ns beslut endast på det sätt, att sammanställningen enligt editionsföreläggandet skall avse de produkter/kombinationer som är avbildade på sidorna 1b, 2b och 4b i bil 3 till Hags' stämningsansökan.

Cykelställfabriken anförde besvär (ombud advokaten Anders Hessle) och yrkade att HD måtte, med undanröjande av HovR:ns beslut, lämna Hags' yrkande om editionsföreläggande utan bifall.

Hags (ombud advokaten Kaj Sandart) bestred bifall till besvären.

Målet avgjordes efter föredragning.

Föredraganden, RevSekr *Olsson*, hemställde i betänkande att HD måtte meddela följande beslut: *Skäl.* De av Hags begärda uppgifterna får anses erforderliga för utredning om de framställda skadeståndsanspråken. Cykelställfabriken innehar, enligt egen uppgift, ordererkännanden och fakturor med underlag av vilka de begärda uppgifterna framgår. Dessa handlingar kan därför antagas äga betydelse som bevis.

De nämnda uppgifterna avser Cykelställfabrikens försäljning av vissa utföringsformer av uterum samt lek- och klätterställningar bestående av separat tillverkade, inbördes kombinerbara byggelement. I målet är upplyst, att Hags och Cykelställfabriken är huvudkonkurrenter på den svenska marknaden i fråga om dylika alster. Med hänsyn till vad som närmare upplysts om marknads- och konkurrensförhållandena i branschen samt till omständigheterna i övrigt, främst den att Cykelställfabriken är ett mindre företag, får de av Hags begärda uppgifterna anses utgöra Cykelställfabrikens yrkeshemlighet. Enligt 38 kap 2§ RB, jämförd med 36 kap 6§ samma balk, föreligger inte skyldighet att i rättegång förete handling innehållande dylika uppgifter, om ej synnerlig anledning därtill förekommer. Domstolen får vid en sådan prövning väga mot varandra de olika intressen, som är i fråga. Om kärande i mål angående skadestånd på grund av upphovsrättsintrång yrkar att svaranden skall åläggas att framlägga uppgifter om sin försäljning av alster som påstås innebära intrång bör för bifall till yrkandet fordras, att domstolen funnit åtminstone viss sannolikhet föreligga för att svaranden begått upphovsrättsintrång. Det är givet, att tillämpningen även av ett så begränsat beviskrav under målets förberedande kan vara vansklig och därför mana

till försiktighet i bedömningen. Detta gäller inte minst om, såsom i förevarande fall, tvist råder inte endast om svaranden begått intrång utan även om kärandens alster överhuvudtaget åtnjuter upphovsrättsligt skydd.

Frågan om synnerlig anledning förekommer för editionsföreläggande bör även bedömas med hänsyn till parternas möjlighet jämlikt stadgandet i 17 kap 5§ 2 st RB att begära mellandom över talan om intrånget och svarandens skyldighet att erlägga skadestånd, medan frågan om skadeståndets storlek får prövas senare försåvitt käromålet inte ogillas i den utbrutna frågan eller parterna inte träffar uppgörelse om skadeståndsbeloppet. Fastställs att svaranden är skadeståndsskyldig, möter givetvis inte några betänkligheter att – om svaranden då inte godvilligt lämnar erforderliga uppgifter för skadeståndets beräknande – ålägga denne att framlägga sådana uppgifter.

Enligt det nyssnämnda lagrummet är en förutsättning för uppdelning av målet genom mellandom att särskiljande av de olika tvistefrågorna är lämplig med hänsyn till utredningen. Tillika gäller att mellandom får meddelas mot parts bestridande endast om synnerliga skäl föreligger.

I detta fall har Hags motsatt sig bifall till Cykelställfabrikens yrkande om mellandom över Hags' talan om intrånget i bolagets upphovsrätt. En dom i denna fråga och om Cykelställfabrikens skadeståndsansvar har varit lämpligt med hänsyn till utredningen. Yrkandet har framställts i ett tidigt skede av rättegången, varvid Cykelställfabriken även förklarat sig beredd att, om bolaget befanns ha gjort sig skyldig till intrång i Hags' upphovsrätt, frivilligt utlämna av Hags begärda uppgifter. Ett mellandomsförfarande kan därför, jämfört med den nu föreliggande situationen, ej antagas ha medfört några särskilda nackdelar för Hags.

På grund av det anförda och vad som förekommit i intrångsfrågan kan sådana skäl ej anses ha förebragts att anledning föreligger att för närvarande ålägga Cykelställfabriken att förete handling innehållande de av Hags begärda uppgifterna. Hags' yrkande om sådant åläggande skall alltså ogillas.

HD:s avgörande. Med ändring av HovR:ns beslut ogillar HD yrkandet om editionsföreläggande.

HD (JustR:n *Brundin*, *Erik Nyman*, *Palm*, *Rydin*, referent, och *Solerud*) fattade följande slutliga beslut: *Skäl.* Hags har vid TR:n yrkat skadestånd av Cykelställfabriken under påstående att fabriken har gjort intrång i Hags' upphovsrätt. Intrånget har enligt Hags bestått i att Cykelställfabriken har tillverkat och marknadsfört plagiat av Hags' leksystem Småland. Hags har preliminärt uppskattat skadans storlek till sammanlagt 1 100 000 kr jämte ränta. Beloppet avser följande poster: 250 000 kr för rättigheternas utnyttjande, 750 000 kr för övrig kommersiell skada och 100 000 kr för förlust av goodwill. Hags har förbehållit sig rätten att höja det fordrade skadeståndet, om utredningen i målet ger anledning till det. För att kunna precisera skadeståndets storlek har Hags vid TR:n, enligt vad som antecknats i protokoll vid förhandling för förberedelse i målet, yrkat att Cykelställfabriken föreläggs att genom intyg av revisor visa datum, volym och pris avseende försäljningar av plagiaten under tiden d 1 jan 1982–d 2 sept 1983.

Cykelställfabriken har vid TR:n bestritt Hags' skadeståndstalan under påstående i huvudsak att Hags' i målet aktuella produkter inte är upphovsrättsligt skyddade och att fabriken i vart fall inte har gjort sig skyldig till intrång. Cykelställfabriken har även bestritt yrkandet om editionsföreläggande. Till stöd härför har Cykelställfabriken åberopat, utöver vad som följer av dess inställning i skadeståndsfrågan, att de av Hags begärda uppgifterna avser yrkeshemlighet vars utlämnande kan skada fabriken allvarligt. Cykelställfabriken har också hävdat att de begärda uppgifterna inte är av betydelse för beräkningen av skadeståndet, eftersom rätten kan tillämpa den allmänna bevisregeln i 35 kap 5§ RB.

Målet i HD gäller endast frågan om editionsföreläggande. Parterna har i målet åberopat ett antal skriftliga utlåtanden. Sålunda har Cykelställfabriken hänfört sig till utlåtanden av professorn Gunnar Karnell och docenten Marianne Levin, medan Hags har hänvisat till utlåtanden av professorn Ulf Bernitz, fd rektorn Åke Huldt och fd kanslichefen Eva Insulander.

En förutsättning för att någon skall kunna åläggas att förete skriftlig handling som han innehar är enligt 38 kap 2§ 1 st RB att handlingen kan antas äga betydelse som bevis. Det förhållandet att rätten under vissa förutsättningar kan, med stöd av 35 kap 5§ RB, uppskatta skadestånd som är föremål för tvist befriar inte parten från skyldigheten att förebringa den utredning som skäligen kan åstadkommas (se NJA II 1943 s 449). Sistnämnda bestämmelse kan således inte åberopas som grund för att den utredning om skadans storlek som Hags' editionsyrkande avser saknar betydelse som bevis. Utredningen får i stället i den mening som avses i 38 kap 2§ 1 st antas ha betydelse som bevis i målet.

De av Hags begärda uppgifterna om Cykelställfabrikens försäljningar måste, särskilt med hänsyn till vad som i målet har upplysts om konkurrensförhållandena på området, sammantagna anses utgöra en Cykelställfabrikens yrkeshemlighet. Enligt 38 kap 2§ 2 st RB, jämfört med 36 kap 6§ samma balk, föreligger inte skyldighet att i rättegång förete handling som innehåller yrkeshemlighet, om det ej finns synnerlig anledning till det.

Vid prövningen huruvida det finns synnerlig anledning att Cykelställfabriken skall behöva röja sin berörda yrkeshemlighet är av betydelse bl a frågan hur väl grundat Hags' påstående om upphovsrättsintrång från fabrikens sida är. I detta hänseende måste – med hänsyn till det men som kan uppkomma för Cykelställfabriken genom ett utlämnande av uppgifterna – förhållandevis stränga krav vara uppfyllda för att editionsyrkandet skall kunna vinna bifall. Den bedömning som nu kan göras på grundval av hittillsvarande utredning ger inte ett sådant utslag till förmån för Hags att det kan anses föreligga synnerlig anledning att ålägga Cykelställfabriken att röja sin yrkeshemlighet.

Det anförda leder till att Hags' yrkande om editionsföreläggande för Cykelställfabriken för närvarande inte kan bifallas.

HD:s avgörande. Med ändring av HovR:ns beslut ogillar HD Hags' yrkande om editionsföreläggande.

Referenten, JustR *Rydin* tillade: Cykelställfabriken yrkade vid TR:n att upphovsrätts- och intrångsfrågorna skulle avgöras för sig genom mellandom, innan beslut fattades i editionsdelen. Hags motsatte sig bifall till detta yrkande och någon mellandom meddelades inte. Om under skadeståndsmålets fortsatta handläggning mellandom kommer att meddelas och skadeståndsskyldighet för Cykelställfabriken därvid skulle fastslås, kommer frågan om åläggande för fabriken att lämna ut de begärda uppgifterna uppenbarligen i ett annat läge än det som nu föreligger. Det kan anmärkas att Cykelställfabriken har förklarat sig beredd att under angivna förutsättning tillhandahålla uppgifterna frivilligt. Skulle däremot Cykelställfabriken i en mellandom befinnas inte vara skadeståndsskyldig, faller editionsfrågan.

HD:s beslut meddelades d 18 juli 1986 (nr SÖ 417).

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En delägare i sk tipsbolag underlät att enligt åtagande lämna in tipskupong som, om den hade deltagit i tipsomgången, skulle ha gett vinst. Han har ansetts härigenom ha av oaktsamhet förorsakat övriga delägare skada men har, med hänsyn till arten av hans uppdrag och de förutsättningar som gällde för uppdragets fullgörande, befunnits ej vara skyldig att utge någon ersättning till dem. 4 kap 2 § jämförd med 2 kap 14 § 1 st lagen (1980:1102) om handelsbolag och enkla bolag.

Birgitta A och åtta andra personer väckte vid *Sollentuna TR* talan mot Tomas S och yrkade att denne skulle åläggas att betala 22 367 kr till dem.

Till grund för sin talan anförde kärandena: Under 1982 överenskom parterna att tillsammans spela på tips. Under tio veckor spelade man ett system om 486 rader. Parterna turades om att insamla insatser och lämna in tipskupongen. Vecka 52 år 1982 hade Tomas S uppdraget att insamla och inge tipskupongen. Omgångens system utföll med 13 rätt jämte 11 tolvor, 50 elvor och 120 tior. En av kärandena, Jan R, kontaktade Tomas S på lördagskvällen per telefon och han och Tomas S diskuterade eventuell utdelning. Nästkommande arbetsdag uppgav Tomas S att han ej lämnat in tipskupongen varför någon vinst således ej förelåg. För det fall kupongen inlämnats hade den utfallit med ett belopp om 24 852 kr netto. – Enär Tomas S träffat överenskommelse med kärandena om att spela i bolag och åtagit sig att inge kupongen samt erhållit erforderliga insatser är han skyldig att ersätta kärandena den uteblivna vinstersättningen.

Tomas S bestred betalningsskyldighet och anförde: Kärandenas uppgifter är i huvudsak riktiga, dock med följande justeringar. Han har aldrig uppfattat parternas samarbete som någon form av bolag. Initiativet till samarbetet togs av Jan R, som kom och frågade honom: "Ska vi spela på tips?" varpå Tomas S svarade: "Ja, varför inte." Parterna är arbetskamrater på Gärdets sjukhus. De andra trodde tydligen att han såsom varande engelsman var hemmastadd i engelsk fotboll och väl skickad att tippa sådana matcher. Samarbetet inleddes i slutet av 1982. Alla satsade 30 kr i veckan. Beloppet lämnades till Tomas S, vanligen innan tipskupongen skulle lämnas in men ibland först senare. Tomas S bestämde sedan på egen hand hur man skulle tippa den aktuella veckan och lämnade in tipskupongen. Dessförinnan tog han dock fotokopior av kupongen och lämnade till de övriga medverkande. Den nu ifrågavarande veckan – som enligt hans minnesbild var vecka 1/1983 – glömde han dock att lämna in kupongen i tid. Han förbisåg att torsdagen, som är den vanligen sista tillåtna inlämningsdagen, var en helgdag. När Jan R kontaktade honom på lördagskvällen hade Tomas S gäster hemma och ville därför inte gå in i någon närmare diskussion rörande sitt misstag.

TR:n (rådmannen *Sterzel*) anförde i dom d 27 maj 1983: *Domskäl.* Av Tomas S:s egna uppgifter framgår att parterna bildat ett enkelt bolag och uppdragit åt honom att varje vecka tippa för ett visst belopp. Den nu ifrågavarande veckan har Tomas S som vanligt uppburit övriga bolagsmäns insatser och iordningställt en tipskupong, varav kopior tillställts de övriga. Det får därefter anses ha ålegat honom att, i enlighet med parternas överenskommelse, inlämna kupongen i tid. Då han underlåtit detta, har han gjort sig skyldig till vårdslöshet och därigenom åsamkat övriga bolagsmän skada, uppgående till yrkat belopp. Käromålet skall då bifallas.

Domslut. Tomas S förpliktas att genast till kärandena utge 22 367 kr.

Tomas S fullföljde talan i *Svea HovR* och yrkade ogillande av käromålet.

Birgitta A och medparter bestred ändring.

HovR:n (hovrättslagmannen *Groll*, hovrättsrådet *Bremberg*, referent, och hovrättsassessorn *Kjellström*) anförde i dom d 11 okt 1984: *Dom-*

Exhibit 3

Åsa Schoening, Translator & Interpreter
44 Rivers Edge Drive
Little Silver, NJ 07739

August 20, 2010

I, Åsa Schoening, hereby certify that to the best of my knowledge, the translation from Swedish into English of the order of the Göta Court of Appeal in the case of Aquatube i Boxholm AB v. Nya Boxholm Produktion Aktiebolag, issued on 18 June 1996, is both accurate and complete.

Åsa Schoening

GÖTA COURT OF APPEAL	**JUDGMENT**	DT 4025
Dept. 4	06/18/1996	T 427/95
Division 43	Jönköping	

APPEALED JUDGMENT
Judgment by Mjölby District Court on 08/17/1995; see Appendix A

PLAINTIFF
Aquatube i Boxholm Aktiebolag, 556462-4731, c/o Sven Erkers, Backen,
590 10 BOXHOLM (identified below as Boxholms Trärör)

Representative: Attorney Sören Ödell, Box 523, 581 06 LINKÖPING

OPPOSITE PARTY
Nya Boxholm Produktion Aktiebolag, 556363-1356, Box 16, 590 10 BOXHOLM
(identified below as Nya Boxholm)

Representative: Attorney Magnus Nedstrand, Box 456, 581 05 LINKÖPING

MATTER
damages

_____

ULTIMATE ORDER OF THE COURT OF APPEAL

Amending the judgment of the District Court with regards to the principal matter, the Court of Appeal obliges Boxholms Trärör to pay to Nya Boxholm damages amounting to SEK fifty thousand (50,000) plus interest in accordance with § 6 of the Law of Interest starting on 22 November 1994 until payment has been made.

The Court of Appeal prohibits Boxholm Trärör under penalty of a fine of SEK ten thousand (10,000) to make use of the confiscated material containing trade secrets in the form of offers and underlying figures for cost estimates (Mjölby Police District; requisition ledger 288/93 item 1 and requisition ledger 289/93 items 1 and 2) and obliges Boxholms Trärör to hand over without ransom this material to Nya Boxholm.

Amending the judgment by the District Court regarding the litigation costs as well, the Court of Appeal relieves Boxholms Trärör from the obligation to compensate Nya Boxholm for litigation costs at the District Court.

Each party shall shoulder its litigation costs at the Court of Appeal.

GÖTA COURT OF APPEAL **JUDGMENT** T 427/95
06/18/1996

CLAIMS BEFORE THE COURT OF APPEAL

Boxholms Trärör has claimed that the Court of Appeal should dismiss upon its merits Nya Boxholm's claim for damages in its entirety and vacate the orders for the imposition of a fine and the handing over of the confiscated material. Furthermore, Boxholms Trärör has claimed relief from the liability to compensate Nya Boxholm for litigation costs at the District Court and the obligation of Nya Boxholm to compensate Boxholms Trärör for litigation costs at the District Court.

Nya Boxholm has opposed any amendment.

The parties have claimed compensation for the litigation costs at the Court of Appeal.

REASONING BY THE COURT OF APPEAL IN SUPPORT OF THE JUDGMENT

Malzoff, Nivum, and Erkers were questioned again under oath and witnesses Högberg, Sållarp, Virdhall, and Magnusson were re-examined . With regards to everything essential, they have all provided information corresponding to that which was recorded in the judgment by the District Court. Furthermore, the tapes of the examinations at the District Court of Bohlin, Andersson, and Berg were played.

The Court of Appeal makes the following assessment.

In accordance with § 1 of the Trade Secrets Protection Act (1990:409, TSPA), a trade secret is the type of information regarding business or operating conditions of the activities of a manufacturer which the manufacturer keeps secret and the revelation of which is intended to cause the manufacturer harm with regards to competition.

Boxholms Trärör has asserted that the information of interest in this case regarding the production of wooden pipes, etc., is not to be considered confidential information in accordance with the TSPA, since it has neither contained any information worthy of protection nor has it been kept sufficiently protected, but instead it has been easily accessible for anyone wanting to study it. Nya Boxholm, however, has maintained that all of the material included in the so-called wooden pipe archive forms a whole – a bank of knowledge – that fulfills the requirements of it bearing reference to the area worthy of protection.

It is the opinion of the Court of Appeal that the latter perspective is too far-reaching. A piece of information that when examined as an individual case does not appear to be confidential may still, if it is documented in an inseparable manner with a confidential piece of information, at some point enjoy the protection in accordance with the TSPA. But it cannot be a question of letting this protection extend to a stand-alone document with information of a general character for the reason that it has a certain relationship to or is included in a collection of other documents containing confidential information. And with respect to confidential information that has been stored in a computer system, one must in the same manner, following an assessment of the individual case, consider whether any part of the material is of such nature that it can be disclosed to everyone, and whether in that case it can be separated without the confidential part of the information being revealed.

Against this background, the Court of Appeal in its review of the information on wooden pipe manufacturing, etc. limited the area deemed worthy of protection in accordance with the TSPA in the following manner. To begin with, it was noted that it had not been made clear through safety instructions, the labeling of material as confidential, or the like, where the limit between trade secrets and other information was to be drawn for the business activities in question. The starting point has therefore been that a piece of information should be seen as constituting a trade secret only provided that it can be considered so essential to Nya Boxholm's activities that the revelation of it would change in a negative direction the company's ability to compete, and that this must have been clear to the employees and others even without any particular clarification by the management.

That which according to Erkers and Högberg constitutes the wooden pipe archive is a large number of binders containing complete documentation of different wooden pipe projects concluded during the period of 1970 – 1992. It was Högberg, and during the last years Erkers, who collected and compiled this material. Since each wooden pipe project is unique, Erkers and Högberg claim that there is no use whatsoever for the drawings and calculations that form a part of the material when a new project is about to be started. Nor is it in their opinion the case – which Malzoff claimed – that the material may be used if a previously constructed wooden pipe needs to be repaired. In fact, repair work requires either that one is able to investigate the damage on site or that the client provides a satisfactory account of what has happened. At that point there is no reason to go back to the archived material and instead it would be easier to let the new information that has emerged form the basis of new drawings and calculations. Both Erkers and Högberg have

expressly explained that they never made use of the archived material in their daily work and instead viewed it as "history." It is not the opinion of the Court of Appeal, which attaches great importance to the statements by Högberg regarding the material, that Nya Boxholm has been able to demonstrate that the information regarding the concluded wooden pipe projects included in the material was so essential to the company's activities that it is worthy of protection as a trade secret.

Another part of the material consists of so-called T-appendices. These appendices, numbering 236, were used by the company when bids were given to clients and during the marketing of wooden pipe products. They contain information on different steps of the wooden pipe production, descriptions of material, delivery regulations, etc. Högberg was responsible for the content and format of these appendices. A fairly large number of copies were made and kept in numerical order in a specific cabinet in an office room. Högberg claims that they do not contain any confidential information at all and that they were distributed in such a manner that practically anyone could get access to them. The Court of Appeal finds – primarily when considering the statements by Högberg – that it has not been demonstrated with regards to the T-appendices either that they should bear reference to the protection-worthy area.

A reference list of pipe deliveries during the period of 1970 – 1990 is according to Malzoff not only a record of references but also – together with the offers in question – a nearly complete client register. Högberg has stated, however, that during his time the company used this list as a part of its marketing. It was sent out to presumed clients for the purpose of getting them interested in wooden pipes as opposed to pipes of steel, cement, etc. Högberg claims that the client circle is very small when it comes to wooden pipe products and that it covers largely only power plants, paper mills, and municipalities. According to Högberg the list of references is therefore not of any use as a client register. It is the opinion of the Court of Appeal that it has not been demonstrated in the case of the reference list either that it should be handled as confidential information.

In addition to the material discussed above, the police confiscated 66 hanging folders in connection with a house search at Boxholms Trärör on 23 November 1993. They contained 226 business documents and were labeled with names of objects according to a specific register (Mjölby Police District's minutes of 11/26/1993, Registration no. K 3126-93, requisition 288/93 item 1; the majority of this material was also available on computer disks that were confiscated at the same time;

see aforementioned minutes, requisition 289/93, items 1 and 2). This material had been kept in three binders labeled "Offers A-H," "Offers I-R," and "Offers S-Ö" at Boxholm Production AB. The material contained all of the company's offers including calculation figures and occurring correspondence with clients of interest. The underlying calculation figures show how the costs of material, work and deliveries were calculated and also contains information on mark-ups in percent regarding contracts, special assignments, transportation, and the objects as a whole. It is the opinion of the Court of Appeal that there is no doubt that this part of the material contains information of such essential interest to Nya Boxholm's activities that it should be protected as a trade secret. In summary, the Court of Appeal has thus concluded that it is only the informational material regarding offers including calculation figures for ongoing projects at the time of the bankruptcy in February of 1993 that should bear reference to the area deemed protection-worthy in accordance with the TSPA .

Nya Boxholm's action for the recovery of damages was directed – not at Erkers – but at Boxholms Trärör. The basis for this action – with reference to §§ 3, 6 and 7 of the TSPA – was claimed to be that Boxholms Trärör through the actions of Erkers effected access to the trade secrets and used them in an improper manner in their own activities. Boxholms Trärör has opposed this, stating in part that the company in the role of a legal person cannot make itself guilty of a punishable act (§ 3, TSPA) and that neither can it have been the employee of Boxholm Produktion AB (§ 7, TSPA), in part that the company has never had any kind of business connection with the bankruptcy estate and that I therefore cannot have been informed in confidence of the bankruptcy estate's possible trade secrets (§ 6, TSPA).

The objections made by Boxholms Trärör against Nya Boxholm's presentation of the grounds of the action for damages are undoubtedly reasonable. In fact, the reference to §§ 3, 6 and 7 is directly misleading. Out of the cited sections, it is only §§ 6 and 7 that in and of themselves could be applicable, and then only if the action had been brought against Erkers alone. Since Nya Boxholm has chosen to bring the action – not against Erkers – but against Boxholms Trärör, § 8 of the TSPA is the only relevant section, i.e. the section according to which the person who intentionally or through negligence uses a trade secret can become liable for damages if he realized or ought to have realized that the confidential information had previously been illegally seized.

Erkers has admitted to obtaining photo copies of the confidential informational material in connection with his planned takeover of the activities of the bankruptcy estate. The purpose thereof was for him to use it at his bank as support material for a loan application. He has claimed that he had the consent of the official receiver to photocopy the material. The receiver has firmly denied giving Erkers permission to do so, however. In view hereof the Court of Appeal finds that Erkers – by copying the material and later placing it at Boxholms Trärör's disposal – revealed the confidential information that he'd gained access to in connection with his business connection with the bankruptcy estate (§ 6, TSPA). But in his role of employee at Boxholms Produktion Aktiebolag he also learned of confidential information under such circumstances that he must have realized that he must not reveal it (§ 7, TSPA).

It is the opinion of the Court of Appeal that the circumstance that Nya Boxholm did not expressly refer to § 8 of the TSPA should not result in the action being dismissed upon its merits. In fact, an overall assessment finds that Nya Boxholm must be considered to have expressed that the basis for the action for damages is that Boxholms Trärör, with Erkers as sole owner, was informed of the trade secrets through him and used the same in an inappropriate manner in its own business.

Liability for damages in accordance with § 8 of the TSPA presupposes that a trade secret has been used without authorization or revealed by the liable person. This amounts to a requirement of a certain activity. By usage is meant that someone in his own activities applies in practice the information that the trade secret consists of and this should be a matter of a commercial usage (see Fahlbeck, Företagshemligheter, konkurrensklausuler och yttrandefrihet [Trade Secrets, non-competition clauses and freedom of speech], Ed. 1:1, 1992 p. 222).

The material of interest here, i.e. offers and calculation figures for ongoing projects at the time of bankruptcy in February of 1993, was found during a house search of Boxholms Trärör's office room and the material was stored there in a systematic manner in a large number of hanging folders and was also available on the computer system. In the opinion of the Court of Appeal, these circumstances combined with the fact that Boxholms Trärör worked with the same type of products and turned to the same group of clients as Nya Boxholm are a strong indication that Boxholms Trärör used the confidential information for an inappropriate purpose in its own business activities.

However, Erkers has firmly denied making any use whatsoever of the material during his contacts with clients in 1993 and has thus not used it for a competitive purpose on any occasion. He has described in great detail the reason why the material was of no importance to him in the new business. He has furthermore stated that he – since he himself drafted the offers and calculation figures in question during his time as head of the wooden pipe unit at Boxholm Produktion AB – was well acquainted with the content of this material and had no need to use it when providing bids on behalf of Boxholms Trärör. Furthermore he has stated in particular that the activities at Boxholm Produktion AB were operated in a completely different manner than those at Boxholms Trärör. At the former company the activities concerned the production as well as the sale of wooden pipes whereas Boxholms Trärör worked exclusively with the sale of this product. The conditions for providing offers and drafting calculation figures were therefore completely different at the two companies and consequently Erkers could not make use of the information about different costs and mark-ups that was found in the material drafted prior to the bankruptcy.

In assessing whether there was any inappropriate use of the confidential informational material on the part of Boxholms Trärör one should at first consider that Erkers – who, as previously demonstrated, -- obtained photocopies of the material for use in connection with a loan application. In view of the interest that he had undisputedly shown in personally taking over the wooden pipe activities from the bankruptcy estate, this information appears reasonable in and of itself. The fact that he thereafter brought this and other informational material on wooden pipe production to his new office facilities, even though the material in his own opinion was outdated and practically worthless, appears to be contradictory in the opinion of the Court of Appeal. This impression is underscored by the letter addressed by Erkers to “all wooden pipe clients” on 1 April 1993. It is indicated in the letter that Erkers has gathered all knowledge, experience and occupational know-how regarding wooden pipes in one company, Boxholms Trärör, which continues the wooden pipe tradition. It should be considered in this context that even Erker’s knowledge constitutes trade secrets to the extent that it involves such information that the Court of Appeal has deemed confidential. Against this background and with particular consideration given to the nature of the informational material, the Court of Appeal finds that Nya Boxholm must be found to have shown that Boxholms Trärör’s activities made disloyal use of the confidential material when bids were provided to e.g. HackåsNäs, Knutshyttan, Gottne, and Brännkvarn’s power plant. The Court of Appeal

therefore finds, as did the District Court, that Boxholms Trärör should compensate Nya Boxholm for the damage that may have arisen.

Nya Boxholm has claimed as the grounds for its action for damages that the company as a result of Boxholms Trärör's inappropriate use of trade secrets in part lost four orders to Boxholm Trärör, in part was forced to reduce its prices for a number of orders obtained in 1993 and 1994, and in part had to bear increased costs for advertising, etc. to inform previous customers of Boxholms Trärör's inappropriate actions.

Boxholms Trärör has contested both that Nya Boxholm had to suffer any damage and that there is any relationship between the alleged damages and the use of trade secrets.

It is undisputed in the case that Boxholms Trärör obtained four orders regarding projects that Boxholm Produktion AB previously had bid on. This circumstance coupled with the condition that the wooden pipe market has few players indicates in and of itself that Nya Boxholm could have obtained the orders if they hadn't gone to Boxholms Trärör. The investigation has shown, however, that the wooden pipe industry competes in particular with pipe manufactures using other types of material, such as plastic and cement. Against this background and since no investigation has been presented that supports the assumption that Nya Boxholm would have obtained any of the orders in question the company's action for damages cannot be sanctioned with regards to these projects.

The right to damages in accordance with § 8 of the TSPA presupposes an immediate connection between the declared damage and the inappropriate use. As far as the investigation shows, Erkers – independently of his access to offers and calculation figures – possessed sufficient personal knowledge to continue running the wooden pipe business on his own. Nor does the investigation support the assumption that his access to the confidential material constituted a necessary condition for him to run a business that competed with Nya Boxholm. Thus, it falls on Nya Boxholm to demonstrate that price adjustments and costs of advertising, etc. were caused by Erker's inappropriate use of the trade secrets and thus that they did not just form a part of

the necessary adjustment to the new competitive situation. No investigation regarding this has been presented. Damages can therefore not be made payable on this basis.

The statements made hereby by the Court of Appeal prove the obvious difficulties, in a case like this one, that are linked to demonstrating what financial damage may arise from the inappropriate use of a trade secret. This does not mean, however, that the person who disloyally uses confidential information to the detriment of someone else should walk free of the liability to pay damages. In fact, § 9 of the TSPA offers the possibility to determine general damages for an attack on the trade secret of a manufacturer. In consideration of Nya Boxholm's interest in enjoying the protection of its trade secrets and in taking into account the benefit that Boxholms Trärör could have drawn from the information, the Court of Appeal finds that the latter company should be obligated to pay out damages amounting to the reasonable sum of SEK 50,000.

In accordance with this outcome Nya Boxholm's request for prohibition under penalty of a fine is sanctioned with regards to the information which has been found before the Court of Appeal to constitute a trade secret. Furthermore, confiscated documents and disks containing this information are to be handed over to Nya Boxholm without any ransom.

Litigation costs

The principal matter in the case has been to determine whether there had been any obligation to pay out damages. Nya Boxholm's understanding of the protective value of the information has only been met with a limited degree of sympathy and in determining the extent of the damages only an insignificant part of the demanded amount was sanctioned. On the whole the Court of Appeal therefore finds that both parties have both won and lost to such a degree that they should shoulder their own costs at the District Court as well as at the Court of Appeal.

GÖTA COURT OF APPEAL **JUDGMENT** T 427/95
06/18/1996

HOW TO LODGE AN APPEAL; see Appendix B.
Appeal no later than 16 July 1996.

[signature]
Lars Åhlén

[signature]
Johan Stenberg

[signature]
Hans Träff

[signature]
Christian von Szalay

Division Head at the Court of Appeal Lars Åhlén, Judges of Appeal Johan Stenberg (Reporter of the Case) and Hans Träff as well as temporary Associate Judge of Appeal Christian von Szalay took part in the decision by the Court of Appeal.

Unanimous

[stamp:]
GÖTA COURT OF APPEAL
Duly certified photocopy
[signature]

[handwritten:]
T 427/95, r. 43 *PJ. CvS*
(ref.)
LÅ – JMS – HT – CvS

[handwr:]
Seen by: **SUPREME COURT**
[initials] Dept. 1

MINUTES
of examination of application
DATE OF ORDER
10/*29*/1996
Stockholm

Enclosure no. [handwr.:] *4*

Case no. T 3237/96

[stamp:]
GÖTA
11/01/1996
COURT OF APPEAL

PRESENT JUSTICES OF THE SUPREME COURT	Gregow, Nyström and Nilsson √ √
PRESENTING JUDGE REFEREE AT THE SUPREME COURT	Tor Olsson
RECORDING CLERK	Axelsson
PARTIES	**PLAINTIFF** Aquatube i Boxholm Aktiebolag, 556462-4731, c/o Sven Erkers, Backen, 590 10 BOXHOLM Representative: Attorney Sören Ödell, Box 523, 581 06 LINKÖPING **OPPOSITE PARTY** Nya Boxholm Produktion Aktiebolag, 556363-1356, Box 16, 590 10 BOXHOLM Representative: Attorney Magnus Nedstrand, Box 465 [sic], 581 05 LINKÖPING
CASE	Damages
APPEALED DECISION	Göta Court of Appeal, Dept. 4, judgment on 18 June 1996, DT 4025

The case is presented.

The Supreme Court finds no reason to pronounce a review dispensation, as a result

of which the judgment by the Court of Appeal shall remain in effect.

[signature]
Gullvi Axelsson

Presented on 10/21/1996

Shown and handed over for execution on 10/*23*/1996

[signature] [signature]
Torkel Gregow Tor Olsson

[stamp:]
Duly certified photocopy:
[signature]

T 427/95 + 43
LA - JMS - HT - CUS

HÖGSTA DOMSTOLEN
Avd 1

PROTOKOLL
vid tillståndsprövning
DAG FÖR BESLUT
1996-10- 29
Stockholm

Aktbil nr 4

Mål nr T 3237/96

GÖTA
1996 -11- 01
HOVRÄTT

NÄRVARANDE JUSTITIERÅD	Gregow, Nyström och Nilsson
FÖREDRAGANDE REVISIONSSEKRETERARE	Tor Olsson
PROTOKOLLFÖRARE	Axelsson

PARTER

KLAGANDE
Aquatube i Boxholm Aktiebolag, 556462-4731,
c/o Sven Erkers, Backen, 590 10 BOXHOLM
Ombud: advokaten Sören Ödell, Box 523, 581 06 LINKÖPING

MOTPART
Nya Boxholm Produktion Aktiebolag, 556363-1356, Box 16,
590 10 BOXHOLM
Ombud: advokaten Magnus Nedstrand, Box 465,
581 05 LINKÖPING

SAKEN Skadestånd

ÖVERKLAGADE AVGÖRANDET Göta hovrätt, avd 4, dom den 18 juni 1996, DT 4025

Målet föredras.

Högsta domstolen finner ej skäl att meddela prövningstillstånd, i följd varav

hovrättens dom skall stå fast.

Gullvi Axelsson

Gullvi Axelsson

Föredraget 1996-10-21

Uppvisat och lämnat för expediering 1996-10- 23

Torkel Gregow Tor Olsson

Fotokopians överensstämmelse med originalet intygas:

GÖTA HOVRÄTT
Avd 4
Rotel 43

DOM
1996-06-18
Jönköping

DT 4025
T 427/95

ÖVERKLAGAD DOM
Mjölby tingsrätts dom 1995-08-17, DT 127; se bilaga A

KLAGANDE
Aquatube i Boxholm Aktiebolag, 556462-4731, c/o Sven Erkers, Backen, 590 10 BOXHOLM (nedan benämnt Boxholms Trärör)

Ombud: advokaten Sören Ödell, Box 523, 581 06 LINKÖPING

MOTPART
Nya Boxholm Produktion Aktiebolag, 556363-1356, Box 16, 590 10 BOXHOLM (nedan benämnt Nya Boxholm)

Ombud: advokaten Magnus Nedstrand, Box 456, 581 05 LINKÖPING

SAKEN
skadestånd

HOVRÄTTENS DOMSLUT

Med ändring av tingsrättens dom i huvudsaken förpliktar hovrätten Boxholms Trärör att till Nya Boxholm utge skadestånd med femtiotusen (50 000) kr jämte ränta enligt 6 § räntelagen från den 22 november 1994 till dess betalning sker.

Hovrätten förbjuder Boxholms Trärör vid vite av tiotusen (10 000) kr att utnyttja i beslag taget material innehållande företagshemligheter i form av offerter och kalkylunderlag (Mjölby polisdistrikt; beslagsliggare 288/93 punkt 1 och beslagsliggare 289/93 punkterna 1 och 2) samt förpliktar Boxholms Trärör att utan lösen överlämna detta material till Nya Boxholm.

Med ändring av tingsrättens dom jämväl ifråga om rättegångskostnader befriar hovrätten Boxholms Trärör från skyldigheten att ersätta Nya Boxholm för rättegångskostnader vid tingsrätten.

Vardera parten skall stå sina rättegångskostnader i hovrätten.

YRKANDEN I HOVRÄTTEN

Boxholms Trärör har yrkat att hovrätten skall ogilla Nya Boxholms skadeståndsyrkande i sin helhet och undanröja besluten om vitesföreläggande och överlämnande av beslagtaget material. Vidare har Boxholms Trärör yrkat befrielse från skyldigheten att ersätta Nya Boxholm för rättegångskostnader i tingsrätten och förpliktande för Nya Boxholm att ersätta Boxholms Trärör för rättegångskostnader i tingsrätten.

Nya Boxholm har bestritt ändring.

Parterna har yrkat ersättning för rättegångskostnader i hovrätten.

HOVRÄTTENS DOMSKÄL

I hovrätten har Malzoff, Nivum och Erkers hörts på nytt under sanningsförsäkran och omförhör har hållits med vittnena Högberg, Sållarp, Virdhall och Magnusson. De har alla i allt väsentligt lämnat uppgifter i enlighet med vad som antecknats i tingsrättens dom. Vidare har bandupptagningarna av vittnesförhören vid tingsrätten med Bohlin, Andersson och Berg spelats upp.

Hovrätten gör följande bedömning.

Enligt 1 § lagen (1990:409) om skydd för företagshemligheter (FHL) avses med företagshemlighet sådan information om affärs- eller driftförhållanden i en näringsidkares rörelse som näringsidkaren håller hemlig och vars röjande är ägnat att medföra skada för honom i konkurrenshänseende.

Boxholms Trärör har gjort gällande att den i målet aktuella informationen om trärörstillverkningen m.m. inte skall betraktas som hemlig information enligt FHL, eftersom den inte innehållit några skyddsvärda uppgifter och inte heller hållits tillräckligt skyddad utan varit lätt åtkomlig för den som velat ta del av den. Nya Boxholm har däremot ansett att allt det material som ingår i det s.k. trärörsarkivet bildar en helhet - en kunskapsbank - som uppfyller kraven på att hänföras till det skyddsvärda området.

Enligt hovrättens mening leder sistnämnda synsätt för långt. En uppgift som vid en bedömning i det enskilda fallet inte anses hemlig kan visserligen, om den på ett oskiljbart sätt dokumenterats tillsammans med en hemlig uppgift, någon gång komma i åtnjutande av skyddet enligt FHL. Men det kan inte komma i fråga att låta ett fristående dokument med uppgifter av allmän karaktär omfattas av detta skydd av den anledningen att det har ett visst samband med eller ingår i en samling av andra dokument som innehåller hemliga uppgifter. Och när det gäller hemlig information som lagrats i ett datasystem måste man på samma sätt efter en bedömning i det enskilda fallet ta ställning till om någon del av materialet är av sådan beskaffenhet att det kan utlämnas till envar och om det i så fall kan särskiljas utan att den hemliga delen av informationen röjs.

Mot denna bakgrund har hovrätten vid en genomgång av informationen om trärörstillverkningen m.m. avgränsat det enligt FHL skyddsvärda området på följande sätt. Inledningsvis har konstaterats att det inte genom säkerhetsinstruktioner, hemligstämpling eller på liknande sätt har klargjorts var gränsen mellan företagshemligheter och andra uppgifter skulle gå i den aktuella verksamheten. Utgångspunkten har därför varit att en uppgift skall anses utgöra en företagshemlighet endast under förutsättning att den kan anses så väsentlig för Nya Boxholms verksamhet att ett röjande av den skulle förändra företagets konkurrensförmåga i negativ riktning och att detta måste ha stått klart för bland annat de anställda även utan särskilt klargörande från ledningens sida.

Det som enligt Erkers och Högberg utgör trärörsarkivet är ett stort antal pärmar som innehåller en fullständig dokumentation av olika trärörsprojekt som avslutats under åren 1970 - 1992. Det är Högberg och under de sista åren Erkers som har samlat och sammanställt detta material. Eftersom varje trärörsprojekt är unikt, har man enligt Erkers och Högberg inte någon som helst användning av de ritningar och beräkningar som finns i materialet när man skall börja ett nytt projekt. Det är inte heller enligt deras mening så - som Malzoff har gjort gällande - att materialet kan komma till användning om det blir aktuellt att reparera ett trärör som man tidigare byggt. Ett reparationsarbete förutsätter nämligen antingen att man kan undersöka skadan på platsen eller att kunden lämnar en tillfredsställande redogörelse för vad som inträffat. Det finns då inte någon anledning att gå tillbaka till arkivmaterialet utan det enklaste är att låta de uppgifter som man fått fram bilda underlag för nya ritningar och beräkningar. Både Erkers och Högberg har

uttryckligen förklarat att de aldrig använde sig av arkivmaterialet i det dagliga arbetet utan betraktade det som "historia". Hovrätten, som fäster stort avseende vid vad Högberg uttalat om detta material, anser inte att Nya Boxholm förmått visa att de uppgifter om avslutade trärörsprojekt som materialet innehåller varit så väsentliga för företagets verksamhet att de är skyddsvärda som en företagshemlighet.

En annan del av materialet utgörs av s.k. T-bilagor. Dessa bilagor, till antalet 236 stycken, har använts av företaget i samband med att anbud lämnades till kunder och vid marknadsföring av trärörsprodukter. De innehåller information om olika moment i trärörstillverkningen, materialbeskrivningar, leveransbestämmelser m.m. Det är Högberg som har svarat för innehållet i och utformningen av dessa bilagor. De kopierades i ganska stort antal och förvarades i nummerordning i ett särskilt skåp i ett kontorsrum. Enligt Högberg innehåller de inte alls någon hemlig information och de spreds på ett sådant sätt att i stort sett vem som helst kunde få tillgång till dem. Hovrätten finner - främst med hänsyn till vad Högberg uppgett - att det inte heller i fråga om T- bilagorna är visat att de bör hänföras till det skyddsvärda området.

En referenslista över tubleveranser under åren 1970 - 1990 är enligt Malzoff inte bara en referensförteckning utan också - tillsammans med aktuella offerter - ett nära nog komplett kundregister. Högberg har emellertid uppgett att företaget under hans tid använde denna lista som ett led i sin marknadsföring. Den sändes ut till presumtiva kunder i syfte att få dem intresserade av trärör i stället för av rör av stål, betong m.m. Enligt Högberg är kundkretsen mycket snäv i fråga om trärörsprodukter och omfattar i stort sett bara kraftverk, pappersbruk och kommuner. Referenslistan har därför enligt Högberg inte någon betydelse som kundregister. Enligt hovrättens mening kan det inte heller när det gäller referenslistan anses visat att den bör behandlas som hemlig information.

Utöver det material som nu har behandlats tog polisen i samband med husrannsakan hos Boxholms Trärör den 23 november 1993 i beslag 66 stycken hängmappar. Dessa innehöll 226 stycken affärshandlingar och var märkta med objektnamn enligt särskild förteckning (Mjölby polisdistrikts protokoll 1993-11-26, D nr K 3126-93, beslag 288/93 punkt 1; större delen av detta material fanns också på datadisketter som samtidigt togs

i beslag, se nämnda protokoll beslag 289/93 punkterna 1 och 2). Hos Boxholm Produktion AB hade detta material förvarats i tre pärmar märkta "Offerter A-H", "Offerter I-R" och "Offerter S-Ö". Materialet innehöll bolagets samtliga offerter med kalkylunderlag och förekommande korrespondens med aktuella kunder. I kalkylunderlagen redovisas hur kostnaderna för material, arbete och leveranser har beräknats och där finns också uppgifter om procentuella vinstpåslag avseende entreprenader, speciella arbeten, frakter och objekten i sin helhet. Enligt hovrättens mening råder det inte någon tvekan om att denna del av materialet innehåller uppgifter av så väsentligt intresse för Nya Boxholms verksamhet att de bör skyddas som företagshemlighet. Sammanfattningsvis har hovrätten således kommit fram till att det endast är det informationsmaterial avseende offerter med kalkylunderlag i vid konkurstillfället i februari 1993 pågående projekt som skall hänföras till det enligt FHL skyddsvärda området.

Nya Boxholms skadeståndstalan har riktats - inte mot Erkers - utan mot Boxholms Trärör. Som grund för denna talan har - med hänvisning till 3, 6 och 7 §§ FHL - angetts att Boxholms Trärör genom Erkers handlande berett sig tillgång till företagshemligheterna och utnyttjat dessa på ett otillbörligt sätt i sin egen verksamhet. Mot detta har Boxholms Trärör invänt dels att bolaget i egenskap av juridisk person inte kan göra sig skyldig till straffbar gärning (3 § FHL) och inte heller kan ha varit arbetstagare hos Boxholm Produktion AB (7 § FHL), dels att bolaget aldrig haft någon som helst affärsförbindelse med konkursboet och därför inte kan ha i förtroende fått del av konkursboets eventuella företagshemligheter (6 § FHL).

De invändningar som Boxholms Trärör har gjort mot Nya Boxholms angivande av grunderna för sin skadeståndstalan har onekligen fog för sig. Hänvisningen till 3, 6 och 7 §§ FHL är nämligen direkt missvisande. Av de åberopade lagrummen är det endast 6 och 7 §§ som i och för sig skulle kunna vara tillämpliga och då endast om talan förts mot Erkers själv. När Nya Boxholm nu har valt att föra talan - inte mot Erkers - utan mot Boxholms Trärör, så är det enda relevanta lagrummet 8 § FHL, d.v.s. det lagrum enligt vilken den som uppsåtligen eller av oaktsamhet utnyttjar en företagshemlighet kan bli skadeståndsskyldig om han insett eller bort inse att den hemliga informationen tidigare angripits olovligen.

Erkers har vidgått att han i samband med sitt planerade övertagande av verksamheten i konkursboet skaffade sig fotokopior av det hemliga informationsmaterialet. Syftet härmed var att han skulle använda det som underlag för en låneansökan hos sin bank. Han har gjort gällande att han hade konkursförvaltarens medgivande till att fotokopiera materialet. Konkursförvaltaren har emellertid bestämt förnekat att han gett Erkers tillstånd härtill. På grund härav finner hovrätten att Erkers - genom att kopiera materialet och senare ställa det till Boxholms Trärörs disposition - har röjt den hemliga information som han fått tillgång till i samband med affärsförbindelsen med konkursboet (6 § FHL). Men han har också i sin egenskap av arbetstagare i Boxholms Produktion Aktiebolag fått del av hemlig information under sådana förhållanden att han måste ha insett att han inte fick avslöja den (7 § FHL).

Den omständigheten att Nya Boxholm inte uttryckligen hänvisat till 8 § FHL bör enligt hovrätten inte föranleda att talan ogillas. Vid en samlad bedömning får Nya Boxholm nämligen anses ha gett uttryck för att grunden för skadeståndstalan är att Boxholms Trärör, med Erkers som ensam delägare, har fått del av företagshemligheterna genom honom och utnyttjat dessa på ett otillbörligt sätt i sin egen verksamhet.

Skadeståndsansvar enligt 8 § FHL förutsätter att en företagshemlighet obehörigt utnyttjats eller röjts av den skadeståndsskyldige. Detta innebär ett krav på en viss aktivitet. Med utnyttjande avses att någon i sin egen verksamhet praktiskt tillämpar den information som företagshemligheten utgör och det skall vara fråga om ett kommersiellt utnyttjande (se Fahlbeck, Företagshemligheter, konkurrensklausuler och yttrandefrihet, uppl. 1:1, 1992 s. 222).

Det material som nu är aktuellt, d.v.s. offerter och kalkylunderlag i pågående projekt vid konkurstillfället i februari 1993, har påträffats vid husrannsakan i Boxholms Trärörs kontorsrum och materialet förvarades där på ett systematiskt sätt i ett stort antal hängmappar och det fanns också tillgängligt i datasystemet. Dessa omständigheter i förening med det förhållandet att Boxholms Trärör sysslade med samma typ av produkter och vände sig till samma kundkrets som Nya Boxholm talar enligt hovrätten med styrka för att Boxholms Trärör har utnyttjat de hemliga uppgifterna i otillbörligt syfte i sin egen verksamhet.

Erkers har emellertid bestämt förnekat att han haft någon som helst användning av materialet vid sina kundkontakter under år 1993 och således inte vid något tillfälle utnyttjat detta i konkurrenssyfte. Han har utförligt redogjort för anledningen till att materialet inte hade någon betydelse för honom i den nya verksamheten. Han har vidare anfört att han - eftersom han själv upprättat de aktuella offerterna och kalkylunderlagen under sin tid som ansvarig chef för trärörsenheten vid Boxholm Produktion AB - var väl förtrogen med innehållet i detta material och inte behövde använda sig av det vid anbudsgivning för Boxholms Trärörs räkning. Vidare har han särskilt framhållit att verksamheten i Boxholm Produktion AB bedrevs på ett helt annat sätt än i Boxholms Trärör. I förstnämnda företag avsåg verksamheten såväl tillverkning som försäljning av trärör medan Boxholms Trärör uteslutande ägnade sig åt försäljning av denna produkt. Förutsättningarna för att avge offerter och upprätta kalkylunderlag var därför helt olika i de båda företagen och Erkers kunde följaktligen inte använda sig av de uppgifter om olika kostnader och vinstpåslag som fanns i det material som upprättats före konkursen.

Vid bedömningen av om det förelegat ett otillbörligt utnyttjande av hemligt informationsmaterial från Boxholms Trärörs sida bör till en början beaktas att Erkers - som tidigare har redovisats - skaffade sig fotokopior av materialet för att användas i samband med en låneansökan. Med hänsyn till det intresse som han obestritt visat för att själv överta trärörsverksamheten från konkursboet framstår denna uppgift som i och för sig trovärdig. Att han därefter tog med sig detta och annat informationsmaterial om trärörstillverkningen till sina nya kontorslokaler, trots att materialet enligt hans egen uppfattning var överspelat och strängt taget värdelöst, framstår enligt hovrättens mening som motsägelsefullt. Detta intryck förstärks av det brev som Erkers tillställde "alla trärörskunder" den 1 april 1993. I brevet anges att Erkers samlat alla kunskaper, erfarenheter och yrkeskunnande om trärör i ett bolag, Boxholms Trärör, som för trärörstraditionen vidare. Att beakta i detta sammanhang är att även Erkers kunskaper är företagshemligheter i den mån det är fråga om sådan information som hovrätten bedömt som hemlig. Mot denna bakgrund och med särskilt beaktande av informationsmaterialets beskaffenhet, finner hovrätten att Nya Boxholm får anses ha visat att den hemliga informationen utnyttjats illojalt i Boxholms Trärörs verksamhet vid anbudsgivningen till bl.a. HackåsNäs, Knutshyttan, Gottne och Brännkvarns kraftstation. Hovrätten

finner sålunda lika med tingsrätten att Boxholms Trärör skall ersätta Nya Boxholm den skada som kan ha uppkommit.

Nya Boxholm har som grund för sitt skadeståndsanspråk gjort gällande att bolaget till följd av Boxholms Trärörs otillbörliga utnyttjande av företagshemligheter dels förlorat fyra order till Boxholm Trärör, dels tvingats sätta ned sina priser vid ett antal erhållna order under åren 1993 och 1994, och dels vidkänts ökade kostnader för annonsering m.m. för att informera tidigare kunder om Boxholm Trärörs otillbörliga förfarande.

Boxholms Trärör har bestritt såväl att Nya Boxholm vidkänts någon skada som att det föreligger något samband mellan påstådda skador och utnyttjandet av företagshemligheterna.

I målet är ostridigt att Boxholms Trärör erhållit fyra order avseende projekt, som Boxholm Produktion AB tidigare lämnat anbud på. Denna omständighet i förening med det förhållandet att trärörsmarknaden har få aktörer talar i och för sig för att Nya Boxholm skulle ha kunnat få beställningarna om dessa inte gått till Boxholms Trärör. Genom utredningen har emellertid framkommit att trärörsindustrin framförallt konkurrerar med rörtillverkare av andra materialslag, som t.ex .plast och betong. Mot denna bakgrund och då någon utredning inte förebringats som ger stöd för antagandet att Nya Boxholm skulle ha fått någon av de aktuella beställningarna kan bolagets talan om skadestånd inte vinna bifall såvitt avser dessa projekt.

Rätten till skadestånd enligt 8 § FHL förutsätter att det föreligger ett omedelbart samband mellan den uppgivna skadan och det otillbörliga utnyttjandet. Såvitt utredningen visar har Erkers - oberoende av tillgången till offerter och kalkylunderlag - i och för sig haft tillräckliga kunskaper för att kunna bedriva trärörsverksamheten vidare på egen hand. Utredningen ger inte heller i övrigt stöd för antagandet att tillgången till det hemliga materialet utgjort en nödvändig förutsättning för honom att kunna driva en med Nya Boxholm konkurrerande verksamhet. Det ankommer sålunda på Nya Boxholm att visa att prisjusteringar och kostnader för annonsering m.m. föranletts av Erkers otillbörliga utnyttjande av företagshemligheterna och således inte bara varit ett led i en

nödvändig anpassning till det nya konkurrensläget. Någon utredning härom har inte förebringats. Skadestånd kan därför inte heller utgå på denna grund.

Vad hovrätten nu har anfört ger vid handen att det är förenat med uppenbara svårigheter att i ett fall som detta visa vilken ekonomisk skada som ett otillbörligt utnyttjande av en företagshemlighet ger upphov till. Det innebär emellertid inte att den som illojalt utnyttjar hemlig information till förfång för annan under alla förhållanden skall gå fri från skadeståndsansvar. I 9 § FHL har nämligen getts möjlighet att bestämma ett allmänt skadestånd för ett angrepp på en näringsidkares företagshemlighet. Med hänsyn till Nya Boxholms intresse av att åtnjuta skydd för sina företagshemligheter och med beaktande av den nytta som Boxholms Trärör kan ha haft av uppgifterna finner hovrätten att sistnämnda bolag bör förpliktas att utge skadestånd med skäligen ansedda 50 000 kr.

Vid denna utgång skall Nya Boxholms begäran om vitesförbud bifallas såvitt avser den information som i hovrätten ansetts utgöra företagshemlighet. Vidare skall i beslag tagna handlingar och disketter med denna information överlämnas till Nya Boxholm utan lösen.

Rättegångskostnader

Huvudsaken i målet har varit att fastställa om skyldighet att utge skadestånd har förelegat. Nya Boxholm har endast i begränsad omfattning vunnit gehör för sin uppfattning om uppgifternas skyddsvärde och har vid skadeståndets bestämmande fått bifall endast till en obetydlig del av yrkat belopp. Sammantaget finner hovrätten därför att båda parter ömsom vunnit och förlorat i sådan grad att de bör bära sina egna rättegångskostnader såväl vid tingsrätten som i hovrätten.

HUR MAN ÖVERKLAGAR; se bilaga B.

Överklagande senast den 16 juli 1996.

Lars Åhlén

Johan Stenberg

Hans Träff

Christian von Szalay

I hovrättens avgörande har deltagit hovrättslagmannen Lars Åhlén, hovrättsråden Johan Stenberg (referent) och Hans Träff samt t.f. hovrättsassessorn Christian von Szalay.

Enhälligt

Exhibit 4

Swedish counsel and detail the trade secret discussions set forth in the declaration, at this point. So, I'm not sure that we would even disagree with it. I guess our main issue with it is that we're not sure how it applies to the issue at hand.

THE COURT: Well, I have decided that I am not going to decide it in the context of these letter submissions on the attorney/client privilege issue. AstraZeneca has set forth numerous arguments as to why the documents should be, the documents should be returned and any other documents should not be deemed to be -- privileged documents should be deemed to have to be produced. And in light of the nature of the arguments and the detail in which they are submitted by AstraZeneca, I am not going to hear any argument today on this issue. Do you believe, Mr. Aldrich, that there's a basis to file a formal motion, with respect to the privilege, you can file a motion.

MR. ALDRICH: We would need to further consider it, your Honor, but I do believe there may be, because I believe it's no longer a privilege issue. We believe what they've set forth now is a new issue based on trade secret law in Sweden, which we don't think is applicable in this case.

THE COURT: All right, well, I'll concede that the privilege is inapplicable. Is that right, Mr. Hendler?

MR. HENDLER: I'm sorry, your Honor, I didn't hear

the beginning.

THE COURT: Well, I think there is a couple double negatives in there. Sorry, let me ask it a different way. Is it your position that the documents are privileged?

MR. HENDLER: Yes.

THE COURT: And then you have a second position that they are also trade secrets?

MR. HENDLER: That's correct.

THE COURT: All right, so there's a lot of positions, I would say there's various layers to your objection to producing the documents that are being sought, as well as to who came or would see the document back that was inadvertently produced.

MR. HENDLER: That is correct, your Honor, including the argument that U.S. Law, Privilege Law ought to apply.

THE COURT: Right, okay. And Mr. Aldrich, you would agree you have not had an opportunity to respond in writing to those various arguments raised by AstraZeneca?

MR. ALDRICH: That is correct, your Honor.

THE COURT: All right, so, I'm not going to decide that issue in or those issues in the context of this informal conference. Any requests for the documents shall be done by way of formal motion on the privilege issues and relay its trade secret issue. Any objection to that?

MR. HENDLER: No, your Honor.

Exhibit 5

(12) **United States Patent**
Karlsson et al.

(10) **Patent No.: US 7,524,834 B2**
(45) **Date of Patent: Apr. 28, 2009**

(54) **STERILE POWDERS, FORMULATIONS, AND METHODS FOR PRODUCING THE SAME**

(75) Inventors: **Ann-Kristin Karlsson**, Staffanstorp (SE); **Cheryl Larrivee-Elkins**, Framingham, MA (US); **Ove Molin**, Huddinge (SE)

(73) Assignee: **AstraZeneca AB**, Södertälje (SE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/993,669**

(22) Filed: **Nov. 27, 2001**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 09/230,781, filed as application No. PCT/SE98/02039 on Nov. 11, 1998, now Pat. No. 6,392,036.

(30) **Foreign Application Priority Data**

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(51) **Int. Cl.**
A61K 31/58 (2006.01)
C07J 53/00 (2006.01)

(52) **U.S. Cl.** **514/174**; 540/100

(58) **Field of Classification Search** 424/489; 540/63, 120; 514/169, 174, 177–182
See application file for complete search history.

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(57) **ABSTRACT**

The invention provides sterile glucocorticosteroids and sterile formulations containing glucocorticosteroid and use thereof in the treatment of an allergic and/or inflammatory condition of the nose or the lungs.

85 Claims, No Drawings

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STERILE POWDERS, FORMULATIONS, AND METHODS FOR PRODUCING THE SAME

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Ser. No. 09/230,781, filed Jan.29, 1999 (now U.S. Pat. No. 6,392,036), which is the National Stage application of International Application No. PCT/SE98/02039, filed Nov. 11, 1998, which claims the benefit of Swedish Patent Application No. 9704186-7, filed Nov. 14, 1997. The contents of these applications are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

This invention relates to a process for sterilization of a powderderd form of a glucocortico-steriod, sterile glucocorticosteroids, sterile formulations containing glucocorticosteroids and use thereof in the treatment of an allergic and/or inflammatory condition of the nose or lungs.

BACKGROUND OF THE INVENTION

Various methods have been proposed in the past for the sterilization of glucocorticosteroids. PT-A-69652 discloses the cold sterilization of micronized glucocorticosteroids using mixtures of ethylene oxide and carbon dioxide, since, according to PT-A-69652, steroids in powder form are not stable at temperatures above 60° C. Specific examples of glucorticosteroids are prednacindone, dexamethasone and prednisolone, and salts, esters and fluoro derivatives thereof, including dexamethasone acetate, dexamethasone phosphate, prednisolone pivalate and 9-alphafluoro prednisolone. However, ethylene oxide is toxic and when it is used to sterilize glucocorticosteroids it has been found that the residual amounts of the ethylene oxide contravene pharmaceutical guidelines which require very low levels of residual ethylene oxide. Accordingly this method has been found to be unsuitable for producing therapeutically acceptable glucocorticosteroids and formulations thereof.

U.S. Pat. No. 3,962,430 discloses a method for the production of sterile isotonic solutions of medicinal agents, which comprises adding the agent to a saturated solution of sodium chloride in water at 100° C. and then heating the mixture at 100-130° C. This method is not suitable for suspensions of fine particles of glucocorticosteroids which are intended for inhalation because the water, and the heating and cooling involved, produce unfavorable changes in the size of the particles. Indeed it can lead to the formation of bridges between the fine particles producing large, hard aggregates which will not deaggregate into the desired fine particles upon administration.

A putative alternative is dry heat sterilization. According to the European Pharmacopoeia (1996, pp. 283-4) a normal heat sterilization process runs at 180° C. for 30 min or at a minimum of 160° C. for at least 2 hours. According to Pharmacopoeia Nordica (1964, pp. 16) such a sterilization can be carried out at 140° C. for 3 hours. However at the temperatures of these processes glucocorticosteroids suffer significant degradation and are subject to changes in their surface structure.

Sterilization by β- or γ-irradiation is also known. Indeed Illum and Moeller in Arch. Pharm. Chemi. Sci., Ed. 2, 1974, pp. 167-174 recommend the use of such irradiation to sterilize glucocorticosteroids. However when such irradiation is used to sterilize certain finely divided, e.g. micronized, glucocorticosteroids, they are significantly degraded.

WO-A-96/09814 to Andaris Ltd. relates to spray-dried particles of a water-soluble material with a mass median particle size of 1 to 10 μm. The aim of the invention is to produce uniform and reproducible particles for use in dry powder inhalers. The water-soluble material is preferably a human protein or a fragment thereof, in natural or recombinant form, e.g. human serum albumin (HSA), alpha-1 antitrypsin or alcohol dehydrogenase. Also combinations of an active material with a carrier were produced e.g. budesonide and lactose. It is stated generally that the microparticles produced can be sterile without teaching how this could or would be achieved nor showing any proof thereof.

WO-A-96/32095 to Astra AB relates to a process for the preparation of respirable particles by dissolving an inhalation compound in a solvent, introducing the resulting solution containing the inhalation compound in droplet form or as a jet stream into an anti-solvent which is miscible with the solvent and which is under agitation. Budesonide with a mass median diameter (MMD) of less than 10 μm is produced with the process. There is no information in WO-A-96/32095 about sterilization or sterile particles.

WO-A-92/11280 to Instytut Farmaceutyczny relates to a method of obtaining (22R) diastereoisomer of budesonide by a condensation reaction followed by crystallizing the crude product of condensation from ethanol. The obtained 21-acetate of budesonide (22R) is hydrolyzed and the product thus obtained is crystallized from ethyl acetate. The content of (22S) diastereoisomer of budesonide is 1% or less. There is no information in WO-A-92/11280 about sterilization or sterile particles.

We have also found that attempts at terminal sterilization of the pharmaceutical formulations, especially suspensions, e.g. aqueous suspensions, of glucocorticosteroids have all proved unsatisfactory. Such suspensions can not normally be sterilized by sterile filtration as most of the particles of glucocorticosteroid will be retained on the filter. We have also shown that moist heat sterilization, e.g. steam treatment of glass vials containing the product, leads to an unacceptable change in particle size.

Various aqueous suspensions of finely divided glucocorticosteroids are known, e.g. the budesonide-containing product known as Pulmicort® nebulising suspension. (Pulmicort® is a trademark of Astra AB of Sweden). Similar formulations of fluticasone propionate are known from WO-A-95/31964.

Accordingly a new process for the sterilization of glucocorticosteroids (and formulations containing them) is required.

Surprisingly we have now found that effective sterilization of dry glucocorticosteroids can be carried out at a significantly lower temperature than that considered necessary for the heat sterilization of other substances. Such sterile glucocorticosteroids can be used in the preparation of sterile formulations containing them.

DESCRIPTION OF THE INVENTION

According to the invention there is provided a process for the sterilization of a glucocorticosteroid, which process comprises heat treating the glucocorticosteroid in the form of a powder at a temperature of from 100 to 130° C. The process is preferably carried out at a temperature of from 110 to 120° C., more preferably at about 110° C., preferably for up to about 24 hours, more preferable up to 10 hours, e.g. from 1 to 10 hours. The process is conveniently carried out under atmospheric conditions, i.e. in air, but may also be carried out under an inert gas atmosphere, e.g. an atmosphere of argon or nitrogen.

Surprisingly we have found that this process kills many more spores when applied to the glucocorticosteroid budesonide than when applied to the comparison substance calcium stearate. Even better results were obtained with the glucocorticosteroid rofleponide.

It is believed, but we do not intend to be limited by this explanation, that the unexpectedly low temperature at which the glucocorticosteroids can be sterilized indicates that the glucocorticosteroid may provide some synergistic effect, when taken together with the heat treatment, in destroying the spores.

The glucocorticosteroid used in the invention is preferably an anti-inflammatory glucocorticosteroid, e.g. for use in nasal and oral inhalation. Examples of glucocorticosteroids which may be used in the present invention include betamethasone, fluticasone (e.g. as propionate), budesonide, tipredane, dexamethasone, beclomethasone (e.g. as dipropionate), prednisolone, fluocinolone, triamcinolone (e.g. as acetonide), momethasone (e.g. as furoate), rofleponide (e.g. as palmitate), flumethasone, flunisolide, ciclesonide, deflazacort, cortivazol, 16α, 17α-butylidenedioxy-6α,9α-difluoro-11β,21-dihydroxy-pregna-1,4-diene-3,20-dione; 6α,9α-difluoro-11β-hydroxy-16α,17α-butylidenedioxy-17β-methylthioandrosta-4-ene-3-one; 16α,17α-butylidenedioxy-6α,9α-difluoro-11β-hydroxy-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-methyl ester; methyl 9α-chloro-6α-fluoro-11β-hydroxy-16α-methyl-3-oxo-17α-propionyloxy-6α,9α-difluoro-11β-hydroxy-16α-methyl-3-oxo-17α-propionyloxy-androsta-1,4-dien-17β-carbothioic acid S-(2-oxo-tetrahydrofuran-3-yl) ester; optionally in their pure isomeric forms (where such forms exist) and/or in the form of their esters, acetals or salts, where applicable. Suitably, use is made of momethasone furoate, beclomethasone dipropionate or fluticasone propionate or glucocorticosteroids with an asymmetric acetal structure, i.e. comprising 16α,17α-butylidenedioxy, such as budesonide, rofleponide or rofleponide palmitate. Preferably, use is made of budesonide, rofleponide or rofleponide palmitate and most preferably of budesonide.

The glucocorticosteroid is preferably used in the form of a finely divided, e.g. micronized, powder, particularly in the form of finely divided particles having a mass median diameter of less than 10 μm, more preferably less than 5 μm. The glucocorticosteroid may alternatively be in an ultra fine form, e.g. having a mass median diameter of less than 1.0 μm. The finely divided particles may be produced by conventional techniques known per se. e.g. by micronization or by direct precipitation. Information about micronization can be found e.g. in "The Theory and Practice of Industrial Pharmacy", Lachman, Liebermann and Klang, 2nd Ed., 1976, Lea & Febiger, Philadelphia, USA.

The temperature, time, batch size and type of sterilizer used will be interdependent. Thus generally the higher the temperature used in the process according to the invention, the less time is required to sterilize the glucocorticosteroid. The process is preferably carried out for no more than 8 hours, e.g. from 1 to 8 hours, when the temperature is greater than about 110° C., more preferably no more than 4 hours. At a temperature of about 120° C. the process is preferably carried out for no more than 4 hours, e.g. from 1 to 4 hours. more preferably no more than 2 hours, e.g. from 1 to 2 hours.

At temperatures of from about 110° C. up to 130° C., a batch of 50 g of glucocorticosteroid may suitably be heat treated from 1 to 4 hours. If desired sub-batches, e.g. of 4×50 g, may be used.

The present process may be carried out such that it results in a more than log 4 reduction in the amount of heat resistant spores. The process of the present invention is suitably carried out such that it results in a log 6 reduction in the amount of heat resistant spores. The present process is preferably carried out such that it results in a more than log 6 reduction, and more preferably such that it results in a more than log 7 reduction in the amount of heat resistant spores.

A different way of characterizing the efficiency of a sterilizing process is by using the D value. The D value, also known as the D_T value, is the time (in minutes) required to reduce ("kill") a standardized population of spores by 90% or 1 log cycle, i.e. to a survival fraction of 1/10, at a specific temperature T (in ° C.).

The present process may be carried out such that the D value is less than about 240 min at the preselected temperature T, wherein T is in the range of from 100 to 130° C. The process of the present invention is suitably carried out such that the D value is less than 150 min at the preselected temperature T. Preferably, the process of the present invention is carried out such that the D value is less than 90 min at the preselected temperature T, and more preferably such that the D value is less than 30 min at the preselected temperature T. T is suitably 100, 110, 120 or 130° C.

The sterilization process is desirably carried out in such a manner that all parts of the bulk of the glucocorticosteroid reaches, and is maintained within, the desired temperature for the desired time.

The present process may be carried out batch wise or continuously, preferably batch wise.

The glucocorticosteroid starting material for the process, which material may be in finely divided form, is suitably substantially dry, i.e. containing less than about 1% (w/w) of water. Preferably, the starting material for the process contains less than 0.5% (w/w) of water, and more preferably less than 0.3% (w/w) of water.

The glucocorticosteroid starting material for the process suitably has a bioburden of less than 50 CFU (colony forming units) per gram. The glucocorticosteroid starting material for the process preferably has a bioburden of less than 10 CFU per gram, more preferably of less than 1 CFU per gram.

According to the invention there is further provided a sterile glucocorticosteroid (e.g. budesonide), suitably dry and preferably in the form of finely divided particles, e.g. having a mass median diameter of less than 10 μm, and more preferably less than 5 μm.

By the term "sterile" we mean a product which meets the criteria of sterility according to the US Pharmacopoeia 23/NF18, 1995, pp. 1686-1690 and 1963-1975, and which provides a therapeutically acceptable glucocorticosteroid and formulations thereof. Further regulations for sterility of the final product include the European Pharmacopoeia (Ph. Eur. 1998, Chapters 2.6.1 and 5.1.1), the British Pharmacopoeia (BP 1993, Appendix XVI A, p. A180 and Appendix XVIII A, p. A 184) and the Japanese Pharmacopoeia (JP, 13th ed., pp. 69-71 and 181-182). Preferably, the therapeutically acceptable glucocorticosteroid and formulations thereof have been produced by a method which provides assurance of sterility according to the US Pharmacopoeia 23/NF18, 1995, pp. 1686-1690 and 1963-1975.

The glucocorticosteroid according to the invention will essentially maintain the same pharmacological activity and physico-chemical properties/its chemical purity and physical form as the starting material from which it is prepared, i.e. the degradation, and especially the chemical degradation, caused by the present sterilization process will be limited.

The glucocorticosteroid according to the invention is preferably at least 98.5% by weight pure, more preferably at least 99% by weight pure, and most preferably at least 99.2% by weight pure.

The invention further provides a sterile glucocorticosteroid, preferably an anti-inflammatory glucocorticosteroid, more preferably budesonide, rofleponide or rofleponide palmitate, and most preferably budesonide, for use in the treatment of an allergic and/or inflammatory condition of the nose or lungs, e.g. chronic obstructive pulmonary disease (COPD), rhinitis or asthma. The invention also provides the use of such a sterile glucocorticosteroid, preferably an anti-inflammatory glucocorticosteroid, more preferably budesonide, in the manufacture of a medicament (preferably a sterile medicament) for use in the treatment of such conditions.

According to the invention there is further provided a sterile pharmaceutical formulation comprising a glucocorticosteroid in an aqueous suspension, wherein the glucocorticosteroid is preferably a sterile finely divided glucocorticosteroid, such as budesonide.

According to the invention there is also provided a sterile pharmaceutical formulation comprising a glucocorticosteroid and one or more pharmaceutically acceptable additives, to diluents or carriers. Examples of such additives include surfactants, pH regulating agents, chelating agents, agents rendering the suspension isotonic and thickening agents.

To obtain an efficient dispersion of the glucocorticosteroid particles in the suspension, a surfactant may be used, optionally in combination with e.g., lecithin. The surfactants may also function as stabilizing agents in the formulations according to the present invention. Examples of suitable surfactants include non-ionic surfactants of the alkyl aryl polyether alcohol type, specifically tyloxapol —a polymer of 4-(1,1,3,3-tetramethylbutyl)phenol with ethylene oxide and formaldehyde. Further suitable surfactants include sorbitan derivatives, e.g. polyoxyethylene sorbitan fatty acid esters, preferably of the polysorbate or Tween™ groups, more preferably polysorbate 80 or polyoxyethylene 20 sorbitan monooleate (Tween™ 80). Suitable surfactants also include polyoxyethylene ethers, especially polyoxyethylene alkyl ethers, preferably pentaethyleneglycol mono n-dodecylether or $C_{12}E_5$. Further suitable surfactants include poloxamers, polyoxyethylene castor oil derivatives, polyvinylalcohol and block copolymers of polyethyleneoxides, polypropyleneoxides, polybutyleneoxides and polyethyleneglycols (PEGs) or mixtures of any of these. Further suitable surfactants include polyethylene glycol derivatives, especially polyethylene glycol 660 hydroxystearate or Solutol™ HS 15, povidone, polyvinylpyrrolidone (PVP) and polyethyleneglycols (PEGs).

The surfactant may be present at about 0.002 to 2% w/w of the formulation. We prefer the polyoxyethylene sorbitan fatty acid esters to be present at about 0.005 to 0.5% w/w, poloxamers at about 0.01 to 2% w/w, and polyoxyethylene alkyl ethers or thepolyoxy-ethylene castor oil derivatives at about 0.01 to 1.0% w/w of the formulation.

The pH of the suspension may be adjusted as required. Examples of suitable pH regulating agents are weak organic acids, e.g. citric acid, strong mineral acids, e.g. hydrochloric acid, and strong alkaline agents. e.g. NaOH. Alternatively, the pH of the system can be adjusted by balancing the acid and salt forms of buffers such as citric acid, sodium citrate, acetic acid, sodium acetate and sodium phosphate. We prefer the formulations intended for inhalation to have a pH in the range of from about 3.5 to about 6.0, more preferably from 4.0 to 5.0, and most preferably from 4.2 to 4.8.

We also prefer the formulation to contain a suitable chelating agent, e.g. disodium edetate (EDTA). The chelating agent may be present at about 0.005 to 0.1% w/w of the formulation.

Agents which make the suspension isotonic may be added. Examples are dextrose, glycerol, mannitol, sodium chloride, potassium chloride and sodium bromide.

In order to form a stable suspension with a minimal tendency to agglomerate or form a sediment, a thickening agent may be included in the formulation. Examples of suitable thickening agents are cellulose derivatives, suitably cellulose ethers, or microcrystalline cellulose. Preferred cellulose ethers include ethylcellulose, ethylmethylcellulose, hydroxyethylcellulose, hydroxyethylmethylcellulose, hydroxyethylethylcellulose, methylcellulose, hydroxymethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose and carboxymethylcellulose (CMC), e.g. the sodium salt thereof. Suitable thickening agents also include cyclodextrin and dextrin. Suitable thickening agents further include xanthan gum, guar gum and carbomer. Preferred thickening agents in the formulations of the invention are povidone, polyvinylpyrrolidone (PVP) and polyethyleneglycols (PEGs).

The thickening agent may be present at about 0.1 to 3.0% w/w of the formulation. Preferably microcrystalline cellulose and sodium carboxymethyl cellulose (CMC) are present at about 0.5 to 2.5%, xanthan gum at about 0.3 to 3%, carbomer at about 0.1 to 2%, guar gum at about 0.3 to 2% and hydroxypropyl methyl cellulose at about 0.5 to 3.0%, w/w of the formulation.

In the suspension the active constituent, e.g. budesonide, is present as small particles, where at least 90% of the small particles have a mass median diameter (MMD) of less than 20 μm, suitably at least 80% less than 10 μm, preferably at least 70% less than 7 μm and most preferably at least 60% less than 4 μm.

We prefer the suspension to contain from about 0.05 to about 20 mg/ml of the glucocorticosteroid. More preferably the suspension contains from 0.08 to 10 mg/ml of the glucocorticosteroid and most preferably from 0.1 to 5 mg/ml of the glucocorticosteroid.

A sterile pharmaceutical formulation comprising a glucocorticosteroid, such as finely divided budesonide, rofleponide or rofleponide palmitate, sterilized according to the present process, can be prepared by mixing the sterilized glucocorticosteroid with any suitable additional ingredient, e.g. a surfactant, a pH regulating or chelating agent, an agent rendering the suspension isotonic or a thickening agent. All components, other than the glucocorticosteroid, can be produced by sterile filtration of their aqueous solutions. The resulting sterile suspension may be stored under an over pressure of a sterile and inert gas, e.g. nitrogen or argon, and should be filled under aseptic conditions into pre-sterilized containers to produce a sterile pharmaceutical product, e.g. using a blow/fill/seal system.

The invention further provides a method for treatment of an inflammatory condition of the nose or lungs by administering to a mammal, especially a human being, suffering from such a condition a therapeutically effective amount of a sterile glucocorticosteroid or a sterile formulation containing a glucocorticosteroid, preferably a sterile formulation containing a sterile glucocorticosteroid produced according to the present invention. More specifically, the invention provides a method for treatment of chronic obstructive pulmonary disease (COPD), rhinitis, asthma or other allergic and/or inflammatory conditions by administering to a mammal, especially a human being, suffering from such a condition a therapeutically effective amount of a sterile glucocorticosteroid or a sterile formulation containing a glucocorticosteroid, preferably a sterile formulation containing a sterile glucocorticosteroid produced according to the present invention.

EXAMPLES

The invention is illustrated by reference to the following Examples which are not intended to limit the invention.

Example 1

Experiments were carried out to determine the effect of heat treatment upon the chemical purity and physical form of samples of micronized budesonide.

Nine 50 g batches of micronized budesonide (sample nos. 2-10 in Table 1 below) were subjected to the heat treatment shown in Table 1 in a dry sterilizer, Lytzen model CB 1200. Sample 1 was not subjected to such treatment and was used as the reference sample. After the treatment the samples were analyzed for chemical and physical properties.

TABLE 1

No.	1	2	3	4	5	6	7	8	9	10
Temp/° C.	—	100	100	100	110	110	110	120	120	120
Time/hours	0	4	6	10	2	4	10	1	2	4
Size/μm	2.0	2.2	2.2	2.2	2.2	2.2	2.3	2.2	2.2	2.3
Size range (10-90%)/μm	2.6	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Epimer A/% by wt	48.8	48.8	48.7	48.7	48.7	48.8	48.7	48.7	48.7	48.7
Budesonide content/% by wt	99.4	99.3	99.3	99.2	99.2	99.3	98.9	99.2	99.2	99.0
Total of known foreign steroids	0.13	0.14	0.16	0.15	0.16	0.15	0.18	0.14	0.15	0.17
Total of unknown foreign steroids	0.04	0.04	0.05	0.05	0.04	0.08	0.18	0.04	0.07	0.16

After the heat treatment there was no change in the Brunauer, Emett and Teller (BET) surface value (as measured using a Micrometrics Gemini 2375 device; see also British Standard 4359 (1969) part 1) of the budesonide or in its X-ray diffraction pattern for each sample compared to sample 1. The size for each sample was measured as the mass median diameter (MMD) using a Coulter counter.

Example 2

The sterilization of budesonide was compared with that of calcium stearate.

Samples of 0.5 g of budesonide and of 0.5 g of calcium stearate were each inoculated with 0.1 ml of a Steris *Bacillus subtilis* (*globigii*) (Lot#LG126B) spore suspension containing 1.5×10^7 spores. Each sample was subjected to a temperature of 110° C. for 3 hours and 10 min in a Baxter Constant Temperature Oven using the same technique as in Example 1. The spore population of the samples was measured and the results obtained are shown below in Table 2.

TABLE 2

Compound	Before	After
Calcium stearate	1.5×10^7 spores	3.3×10^6 spores
Budesonide	1.5×10^7 spores	<10 spores

As a result of the heat treatment, a spore log reduction of greater than 6.2 was obtained in the inoculated sample of budesonide, whereas the log reduction was less than 0.7 in the inoculated sample of calcium stearate.

Example 3

Tests were performed to evaluate the heat resistance of various naturally occurring microorganisms.

Samples of 0.5 g of budesonide powder were each inoculated with approximately 10^2-10^3 viable ATCC microorganisms in 120 ml open-ended polypropylene container. Each sample was subjected to a temperature of 110° C. for 3 hours and 10 min. The microorganism population of the samples was measured before and after heat treatment and the results obtained are shown below in Table 3.

TABLE 3

Microorganism	Before	After
E. coli	450	0
B. subtilis ATCC 6633	300	0
Salmonella typhi	270	0
C. albicans	780	0
A. niger	260	0
M. luteus	300	0
S. epidermidis	240	0
C. sporegenes	160	0
Ps. Aeruginosa	350	0
B. subtilis ATCC 6633	1.2×10^5	1[1]

[1]A singular *bacillus* species was found, verified by Gram stain in the 10^0 dilution plate.

As is evident from Table 3, heat treatment of budesonide at 110° for 3 hours and 10 min, is an effective sterilizing method for a substantial variety of microorganisms.

Example 4

A formulation comprising finely divided budesonide sterilized by the method of Example 2, and meeting the criteria of sterility according to the US Pharmacopoeia 23/NF18, 1995, was prepared by mixing the following ingredients:

TABLE 4

Micronized budesonide	0.125 mg
Disodium edetate	0.1 mg
Sodium chloride	8.5 mg
Polysorbate 80	0.2 mg
Anhydrous citric acid	0.28 mg

TABLE 4-continued

Sodium citrate	0.5 mg
Purified water	to 1 ml

All the components, other than the budesonide, were produced by sterile filtration of their aqueous solutions and an appropriate volume of the resulting suspension (about 2 ml) was filled under aseptic conditions into pre-sterilized 5 ml containers to produce a sterile product.

The resulting suspension may be stored under an overpressure of sterile nitrogen and may be filled into containers using a blow/fill/seal system.

Example 5

A sterile formulation comprising finely divided budesonide sterilized by the method of Example 2, can be prepared by mixing the following ingredients:

TABLE 5

Micronized budesonide	2-3 mg
Disodium edetate	0.1 mg
Sodium chloride	8.5 mg
Stabilizing agent	0.02-2 mg
Anhydrous citric acid	0.28 mg
Sodium citrate	0.5 mg
Purified water	to 1 ml

All the components, other than the budesonide, can be produced by sterile filtration of their aqueous solutions and an appropriate volume of the resulting suspension (about 2 ml) filled under aseptic conditions into pre-sterilized 5 ml containers to produce a sterile product.

The resulting suspension may be stored under an overpressure of sterile nitrogen and may be filled into containers using a blow/fill/seal system.

Example 6

5 g of micronized budesonide was inoculated with approximately 2 ml of a spore suspension of *Bacillus subtilis*.

The substance and the spore suspension were mixed and dried for approximately 3 hours at 55° C. The inoculated and dried budesonide was mixed with 20-40 g of non-inoculated micronized budesonide.

5 g portions of this sample were heat treated at 100° C., 110° C. or 120° C. in a Heraeus ST 5060 heating apparatus. A 1 g sample was withdrawn after various heating times at the respective heating temperatures. Each such 1 g sample was transferred to 10 ml of dilution medium pH 7.2. Appropriate dilutions were made in 0.1% Peptone Aqueous solution and the number of spores/g were determined by a pour plate technique according to US Pharmacopoeia 23/NF18, 1995, pp. 1681-1686, especially p. 1684.

The number of spores before heat treatment were determined in samples heated at 80° C. for 10 min in order to kill the vegetative cells.

The results are shown in Table 6. where the D_T value is the amount of time in minutes required to obtain a log 1 reduction in the number of spores before and after heat treatment at the temperature T (in ° C.).

TABLE 6

	Heating at 100° C.			
	80° C.	Heating time at 100° C.		
	10 min	15 min	45 min	75 min
spores/g	6.5×10^6	4.8×10^3	7.1×10^2	1.7×10^2
log spores/g	6.81	3.68	2.85	2.23
	Heating at 110° C..			
	80° C.	Heating time at 110° C.		
	10 min	5 min	15 min	20 min
spores/g	2×10^6	2.08×10^4	9.25×10^2	3.55×10^2
log spores/g	6.20	4.32	2.97	2.55
	Heating at 120° C.			
	80° C.	Heating time at 120° C.		
	10 min	4 min	6 min	8 min
spores/g	1.5×10^6	1.9×10^2	5.5×10^1	2×10^1
log spores/g	6.19	2.28	1.74	1.30

D_{100} = 41.5 min; correlation coefficient = −0.0996 This means that it takes 6 × 41.5 minutes to obtain a log 6 reduction in the number of spores at a temperature of 100° C.
D_{110} = 8.3 min; correlation coefficient = −0.995 This means that it takes 6 × 8.3 minutes to obtain a log 6 reduction in the number of spores at a temperature of 110° C.
D_{120} = 4.1 min; correlation coefficient = −0.998 This means that it takes 6 × 4.1 minutes to obtain a log reduction in the number of spores at a temperature of 120° C.

Example 7

1 g of micronized budesonide, prednisolone and beclomethasone dipropionate and 0.5 g of rofleponide were inoculated with a different spore suspension to the one used in Example 6.

The samples were heat treated at 110° C. A sample was withdrawn after various heating times. The number of spores/g were determined by a pour plate technique according to US Pharmacopoeia 23/NF18, 1995, pp. 1681-1686, especially p. 1684.

From the number of spores before and after heat treatment the log reduction of spores and decimal reduction time (time needed at a specified temperature to reduce the number of microorganisms with one log) was calculated.

The results are shown in Table 7.

TABLE 7

Heating at 110° C.	
Glucocorticosteroid	D_{110} value in min
Budesonide	41
Rofleponide	9.8
Beclomethasone dipropionate	72.7
Prednisolone	73.8

Table 7 clearly shows that the present process is very efficient in reducing the number of spores in samples containing glucocorticosteroids. The process is especially efficient with budesonide and rofleponide. In fact analysis conducted on a full 1.0 g sample of rofleponide yielded total kill at very short cycle times (≧5 minutes at 110° C.), where a D_{110} value could not be calculated.

Comparative Example 8

Irradiation

About 3 g of micronized budesonide substance stored in a plastic container, were subjected to irradiation. The substance was exposed to β-irradiation at 2.5 to 25 kGy and γ-irradiation at 8 to 32 kGy. After the exposure the budesonide content and the amount of related substances were determined by liquid chromatography. The chemical stability of budesonide was considered to be the most critical parameter to study.

TABLE 8

Stability of micronized budesonide substance during sterilization by irradiation

Exposure Intensity (kGy)	Ref. i)	β 2.5	β 5	β 10	β 17	β 25	γ 7.8	γ 31.9
Budesonide content (%)	99.5-99.8	99.1	98.9	98.9	98.8	98.8	97.9	95.0
Related substances								
Total of known foreign steroids	0.13-0.15	0.19	0.19	0.18	0.20	0.21	0.34	0.51
Total of unknown foreign steroids	0.03-0.04	0.19	0.24	0.26	0.36	0.43	0.68	1.8

i) The analysis was done on different days and the reference was analyzed at all occasions

From the results in Table 8, it can be seen that the budesonide content decreases in samples exposed to β- and γ-irradiation. Several new degradation products were observed, especially for the γ-irradiated sample. In addition the mass balance for both β- and γ-irradiated samples is poor. The budesonide content has decreased by 0.5-4.6 percent, when exposed to β- or γ-irradiation.

It can be concluded that micronized budesonide can not be satisfactorily sterilized with β- or γ-irradiation, due to significant chemical degradation.

The invention claimed is:

1. A pharmaceutically acceptable, micronized powder composition at least 98.5% by weight of which is pure budesonide or an ester, acetal or salt thereof, wherein the composition meets the criteria of sterility according to the US Pharmacopoeia 23/NF18, 1995, pages 1686-1690 and 1963-1975.

2. The composition of claim 1, wherein at least 98.5% of the composition is pure budesonide.

3. The composition of claim 1, wherein at least 99% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

4. The composition of claim 1, wherein at least 99.2% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

5. The composition of claim 1, wherein the composition is in the form of particles having a mass median diameter (MMD) of less than 10 μm.

6. The composition of claim 5, wherein the particles have a MMD of less than 5 μm.

7. The composition of claim 5, wherein the particles have a MMD of less than 1 μm.

8. The composition of claim 5, wherein at least 99% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

9. The composition of claim 5, wherein at least 99.2% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

10. The composition of claim 1, wherein the composition is in the form of particles at least 80% of which have a MMD of less than 10 μm.

11. The composition of claim 10, wherein at least 99% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

12. The composition of claim 10, wherein at least 99.2% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

13. The composition of claim 10 wherein at least 70% of the particles have a MMD of less than 7 μm.

14. The composition of claim 13, wherein at least 99% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

15. The composition of claim 13, wherein at least 99.2% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

16. The composition of claim 10 wherein at least 60% of the particles have a MMD of less than 4 μm.

17. The composition of claim 16, wherein at least 99% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

18. The composition of claim 16, wherein at least 99.2% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

19. The composition of claim 1, wherein the budesonide is isomerically pure.

20. The composition of claim 19, wherein the budesonide is in the form of the (22R) diastereoisomer.

21. A method for the treatment of an inflammatory condition, the method comprising administering to a mammal suffering from such a condition a therapeutically effective amount of the composition of claim 1.

22. A method for the treatment of an inflammatory condition, the method comprising administering to a mammal suffering from such a condition a therapeutically effective amount of the composition of claim 2.

23. The method of claim 21, wherein the mammal is a human being.

24. A method for the treatment of chronic obstructive pulmonary disease (COPD), the method comprising administering to a mammal suffering from COPD a therapeutically effective amount of the composition of claim 1.

25. A method for the treatment of COPD, the method comprising administering to a mammal suffering from COPD a therapeutically effective amount of the composition of claim 2.

26. The method of claim 24, wherein the mammal is a human being.

27. A method for the treatment of rhinitis, the method comprising administering to a mammal suffering from rhinitis a therapeutically effective amount of the composition of claim 1.

28. A method for the treatment of rhinitis, the method comprising administering to a mammal suffering from rhinitis a therapeutically effective amount of the composition of claim 2.

29. The method of claim 27, wherein the mammal is a human being.

30. A method for the treatment of asthma, the method comprising administering to a mammal suffering from asthma a therapeutically effective amount of the composition of claim 1.

31. A method for the treatment of asthma, the method comprising administering to a mammal suffering from asthma a therapeutically effective amount of the composition of claim 2.

32. The method of claim 30, wherein the mammal is a human being.

33. A method for the treatment of an allergic condition, the method comprising administering to a mammal suffering from an allergic condition a therapeutically effective amount of the composition of claim 1.

34. A method for the treatment of an allergic condition, the method comprising administering to a mammal suffering from an allergic condition a therapeutically effective amount of the composition of claim 2.

35. The method of claim 33, wherein the mammal is a human being.

36. The method of claim 21, wherein the budesonide is isomerically pure.

37. The method of claim 36, wherein the budesonide is in the form of the (22R) diastereoisomer.

38. A pharmaceutically acceptable, sterilized powder composition at least 98.5% by weight of which is pure budesonide or an ester, acetal or salt thereof, wherein the sterilized powder composition was produced by sterilization of viable-microorganism-containing particles of budesonide or an ester, acetal or salt thereof.

39. The composition of claim 38, wherein at least 98.5% by weight of the composition is pure budesonide.

40. The composition of claim 38, at least 99% by weight of which is pure budesonide or an ester, acetal or salt thereof.

41. The composition of claim 38, at least 99.2% by weight of which is pure budesonide or an ester, acetal or salt thereof.

42. The composition of claim 41, wherein the sterilization was accomplished by a method comprising heat sterilization.

43. The composition of claim 42, wherein the heat sterilization was carried out in air.

44. The composition of claim 42, wherein the heat sterilization was carried out under an inert gas atmosphere.

45. The composition of claim 42, wherein the heat sterilization was accomplished at a temperature of 100 to 130° C.

46. The composition of claim 42, wherein the heat sterilization was accomplished at a temperature of 110 to 120° C.

47. The composition of claim 42, wherein the heat sterilization was accomplished at a temperature of 110° C.

48. The composition of claim 38, wherein the budesonide is isomerically pure.

49. The composition of claim 48, wherein the budesonide is in the form of the (22R) diastereoisomer.

50. A pharmaceutically acceptable suspension consisting of a micronized powder composition at least 98.5% by weight of which is pure budesonide or an ester, acetal or salt thereof, suspended in an aqueous solution, wherein the suspension meets the criteria of sterility according to the US Pharmacopoeia 23/NF18, 1995, pages 1686-1690 and 1963-1975.

51. The pharmaceutically acceptable suspension of claim 50, wherein at least 98.5% by weight of the micronized powder composition is pure budesonide.

52. The pharmaceutically acceptable suspension of claim 50, wherein at least 99% by weight of the micronized powder composition is pure budesonide or an ester, acetal or salt thereof.

53. The pharmaceutically acceptable suspension of claim 50, wherein at least 99.2% by weight of the micronized powder composition is pure budesonide or an ester, acetal or salt thereof.

54. The suspension of claim 50, wherein one or more pharmaceutically acceptable ingredients selected from the group consisting of surfactants, pH regulating agents, chelating agents, agents that make the suspension isotonic, and thickening agents are dissolved in the aqueous solution.

55. The suspension of claim 54 comprising a surfactant that is a non-ionic surfactant, a sorbitan derivative, a polyoxyethylene ether, a polyoxyethylene castor oil derivative, or polyoxyethylene glycol, dissolved in the aqueous solution.

56. The suspension of claim 55, wherein the surfactant is present at about 0.002 to 2% w/w of the suspension.

57. The suspension of claim 55, wherein the surfactant is tyloxapol; polysorbate 80; or polyethylene glycol 660 hydroxystearate.

58. The suspension of claim 54 comprising a pH regulating agent that is a weak organic acid, mineral acid, strong alkaline agent or buffer.

59. The suspension of claim 58, wherein the pH regulating agent is citric acid, hydrochloric acid, NaOH, or sodium citrate.

60. The suspension of claim 58, wherein the suspension has a pH of about 3.5 to 6.0.

61. The suspension of claim 58, wherein the suspension has a pH of about 4.0 to 6.0.

62. The suspension of claim 58, wherein the suspension has a pH of about 4.2 to 4.8.

63. The suspension of claim 54, wherein a chelating agent is present at about 0.005 to 0.1% w/w of the suspension.

64. The suspension of claim 63, wherein the chelating agent is disodium edetate (EDTA).

65. The suspension of claim 54 comprising dextrose, glycerol, mannitol, or sodium chloride in an amount to make the solution isotonic.

66. The suspension of claim 54, wherein the aqueous solution comprises a thickening agent constituting about 0.1 to 3.0% w/w of the suspension.

67. The suspension of claim 66, wherein the thickening agent is ethyl cellulose, ethylmethylcellulose, cyclodextrin, dextrin, xanthan gum, providone, polyvinyiprovidone (PVP) or polyethyleneglycol (PEG).

68. A method for the treatment of an inflammatory condition, the method comprising administering to a mammal suffering from such a condition a therapeutically effective amount of the suspension of claim 50.

69. A method for the treatment of an inflammatory condition, the method comprising administering to a mammal suffering from such a condition a therapeutically effective amount of the suspension of claim 51.

70. The method of claim 68, wherein the mammal is a human being.

71. A method for the treatment of COPD, the method comprising administering to a mammal suffering from COPD a therapeutically effective amount of the suspension of claim 50.

72. A method for the treatment of COPD, the method comprising administering to a mammal suffering from COPD a therapeutically effective amount of the suspension of claim 51.

73. The method of claim 71, wherein the mammal is a human being.

74. A method for the treatment of rhinitis, the method comprising administering to a mammal suffering from rhinitis a therapeutically effective amount of the suspension of claim 50.

75. A method for the treatment of rhinitis, the method comprising administering to a mammal suffering from rhinitis a therapeutically effective amount of the suspension of claim 51.

76. The method of claim 74, wherein the mammal is a human being.

77. A method for the treatment of asthma, the method comprising administering to a mammal suffering from asthma a therapeutically effective amount of the suspension of claim 50.

78. A method for the treatment of asthma, the method comprising administering to a mammal suffering from asthma a therapeutically effective amount of the suspension of claim 51.

79. The method of claim 77, wherein the mammal is a human being.

80. A method for the treatment of an allergic condition, the method comprising administering to a mammal suffering from an allergic condition a therapeutically effective amount of the suspension of claim 50.

81. A method for the treatment of an allergic condition, the method comprising administering to a mammal suffering from an allergic condition a therapeutically effective amount of the suspension of claim 51.

82. The method of claim 80, wherein the mammal is a human being.

83. A pharmaceutically acceptable suspension consisting of a sterilized powder composition at least 98.5% by weight of which is pure budesonide or an ester acetal or salt thereof, suspended in an aqueous solution, wherein the sterilized powder composition was produced by sterilization of viable-microorganism-containing particles of budesonide or an ester, acetal or salt thereof, wherein the suspension meets the criteria of sterility according to the US Pharmacopoeia 23/NF18, 1995, pages 1686-1690 and 1963-1975.

84. The pharmaceutically acceptable suspension of claim 83, wherein at least 98.5% by weight of the powder composition is pure budesonide.

85. The pharmaceutically acceptable suspension of claim 83 wherein at least 99% by weight of the powder composition is pure budesonide or an ester, acetal or salt thereof.

* * * * *

Exhibit 6

1801 Basic Patent Cooperation Treaty (PCT) Principles [R-6] - 1800 Patent Cooperation Treaty

1801 Basic Patent Cooperation Treaty (PCT) Principles [R-6]

I. MAJOR CONCEPTS OF THE PCT

The Patent Cooperation Treaty (PCT) enables the U.S. applicant to file one application, "an international application," in a standardized format in English in the U.S. Receiving Office (the U.S. Patent and Trademark Office), and have that application acknowledged as a regular national or regional filing in as many Contracting States to the PCT as the applicant "designates" or "elects," that is, names, as countries or regions in which patent protection is desired. (For international applications filed on or after January 1, 2004, the filing of an international application will automatically constitute the designation of all contracting countries to the PCT on that filing date.) In the same manner, the PCT enables foreign applicants to file a PCT international application, designating the United States of America, in their home language in their home patent office and have the application acknowledged as a regular U.S. national filing. The PCT also provides for an international search report and written opinion (for international applications filed on or after January 1, 2004) that are established normally at 16 months from the priority date, and publication of the international application after 18 months from the priority date. Upon payment of national fees and the furnishing of any required translation, usually 30 months after the filing of any priority application for the invention, or the international filing date if no priority is claimed, the application will be subjected to national procedures for granting of patents in each of the designated countries. For any countries remaining whose national laws are not compatible with the 30 month period set forth in PCT Article **22**(1), the filing of a demand for an international preliminary examination electing such countries within 19 months from the priority date will result in an extension of the period for entering the national stage to 30 months from the priority date. An up-to-date list of such countries may be found on WIPO's web site (www.wipo.int/pct/en/index.html). A brief description of the basic flow under the PCT is provided in MPEP § **1842**.

The PCT offers an alternative route to filing patent applications directly in the patent offices of those countries which are Contracting States of the PCT. It does not preclude taking advantage of the priority rights and other advantages provided under the Paris Convention and the WTO administered Agreement on Trade-

Related Aspects of Intellectual Property (TRIPS Agreement). The PCT provides an additional and optional foreign filing route to patent applicants.

The filing, search and publication procedures are provided for in Chapter I of the PCT. Additional procedures for a preliminary examination of PCT international applications are provided for in optional PCT Chapter II.

In most instances a national U.S. application is filed first. An international application for the same subject matter will then be filed subsequently within the priority year provided by the Paris Convention and the priority benefit of the U.S. national application filing date will be claimed.

II. RECEIVING OFFICE (RO)

The international application (IA) must be filed in the prescribed receiving Office (RO)(**PCT Article 10**). The United States Patent and Trademark Office will act as a receiving Office for United States residents and nationals (**35 U.S.C. 361(a)**). Under **PCT Rule 19.1(a)(iii)**, the International Bureau of the World Intellectual Property Organization will also act as a Receiving Office for U.S. residents and nationals. The receiving Office functions as the filing and formalities review organization for international applications. International applications must contain upon filing the designation of at least one Contracting State in which patent protection is desired and must meet certain standards for completeness and formality (**PCT Articles 11(1)** and **14(1)**).

Where a priority claim is made, the date of the earlier filed national application is used as the date for determining the timing of international processing, including the various transmittals, the payment of certain international and national fees, and publication of the application. Where no priority claim is made, the international filing date will be considered to be the "priority date" for timing purposes (**PCT Article 2(xi)**).

The international application is subject to the payment of certain fees within 1 month from the date of filing. The receiving Office will grant an international filing date to the application, collect fees, handle informalities by direct communication with the applicant, and monitor all corrections (**35 U.S.C. 361(d)**). By 13 months from the priority date, the receiving Office should prepare and transmit a copy of the international application, called the search copy (SC), to the International Searching Authority (ISA); and forward the original, called the record copy (RC), to the International Bureau (IB) (**PCT Rules 22.1** and **23**). A second copy of the international application, the home copy (HC), remains in the receiving Office (**PCT Article 12(1)**). Once the receiving Office has transmitted copies of the application, the International Searching Authority becomes the focus of international processing.

III. INTERNATIONAL SEARCHING AUTHORITY (ISA)

The basic functions of the International Searching Authority (ISA) are to conduct a prior art search of inventions claimed in international applications; it does this by searching in at least the minimum documentation defined by the Treaty (**PCT**

Articles 15 and **16** and **PCT Rule 34**), and for international applications filed on or after January 1, 2004, to issue a written opinion (PCT Rule **43*bis***) which will normally be considered to be the first written opinion of the International Preliminary Examining Authority where international preliminary examination is demanded. See PCT Rule **66.1*bis***.

For most applications filed with the United States Receiving Office, the applicant may choose (in the Request form) * the U.S. Patent and Trademark Office*>,< the European Patent Office>, or the Korean Intellectual Property Office< to act as the International Searching Authority. However, the European Patent Office may not be competent to act as an International Searching Authority for certain applications filed by nationals or residents of the United States. See MPEP § **1840.01** for a discussion of applications and subject matter that will not be searched by the European Patent Office. The International Searching Authority is also responsible for checking the content of the title and abstract (**PCT Rules 37.2** and **38.2**).

An international search report (ISR), and for international applications filed on or after January 1, 2004, a written opinion, will normally be issued by the International Searching Authority within 3 months from the receipt of the search copy (usually about 16 months after the priority date) (**PCT Rule 42**). Copies of the international search report and prior art cited will be sent to the applicant by the ISA (**PCT Rules 43** and **44.1**). The international search report will contain a listing of documents found to be relevant and will identify the claims in the application to which they are pertinent. In applications filed on or after January 1, 2004, the ISA will normally issue a written opinion as to whether each claim appears to satisfy the PCT Article **33** criteria of "novelty," "inventive step," and "industrially applicable." The written opinion may also indicate defects in the form or content of the international application under the PCT articles and regulations, as well as any observations the ISA wishes to make on the clarity of the claims, the description, and the drawings, or on the question of whether the claims are fully supported by the description.

Once the international search report and written opinion are established, the ISA transmits one copy of each to the applicant and the International Bureau, and international processing continues before the International Bureau.

IV. INTERNATIONAL BUREAU (IB)

The basic functions of the International Bureau (IB) are to maintain the master file of all international applications and to act as the publisher and central coordinating body under the Treaty. The World Intellectual Property Organization (WIPO) in Geneva, Switzerland performs the duties of the International Bureau.

If the applicant has not filed a certified copy of the priority document in the receiving Office with the international application, or requested upon filing that the receiving Office prepare and transmit to the International Bureau a copy of the prior U.S. national application, the priority of which is claimed, the applicant must submit such a document directly to the International Bureau or the receiving Office not later than 16 months after the priority date (**PCT Rule 17**). The request (Form PCT/RO/101) contains a box which can be checked requesting that the receiving Office prepare

the certified copy. This is only possible, of course, if the receiving Office is a part of the same national Office where the priority application was filed.

The applicant has normally 2 months from the date of transmittal of the international search report to amend the claims by filing an amendment and may file a brief statement explaining the amendment directly with the International Bureau (**PCT Article 19** and **PCT Rule 46**). The International Bureau will then normally publish the international application along with the search report and any amended claims at the expiration of 18 months from the priority date (**PCT Article 21**). The written opinion, on the other hand, will not be made publicly available until the expiration of 30 months from the priority date. See PCT Rule **44*ter***. The international publication includes a front page containing bibliographical data, the abstract, and a figure of the drawing (**PCT Rule 48**). The publication also contains the search report and any amendments to the claims submitted by the applicant. If the application is published in a language other than English, the search report and abstract are also published in English. The International Bureau publishes a *PCT Gazette* in the French and English languages which contains information similar to that on the front pages of published international applications, as well as various indexes and announcements (**PCT Rule 86**). The International Bureau also transmits copies of the publication of the international application to all designated Offices that have requested to receive the publication (PCT Article **20**, PCT Rule **47**, and PCT Rule **93*bis*.1)**.

V. DESIGNATED OFFICE (DO) and ELECTED OFFICE (EO)

The designated Office is the national Office (for example, the USPTO) acting for the state or region designated under Chapter I. Similarly, the elected Office is the national Office acting for the state or region elected under Chapter II.

PCT Article **22**(1) was amended, effective April 1, 2002, to specify that a copy of the international application, a translation thereof (as prescribed), and the national fee are due to the designated Office not later than at the expiration of 30 months from the priority date. Accordingly, the time period for filing the copy of the international application, the translation, and the fee under PCT Article **22** is now the same as the 30 month time period set forth in PCT Article **39**. The USPTO has adopted the 30 month time limit set forth in PCT Article **22**(1). Most Contracting States have changed their national laws for consistency with PCT Article **22**(1) as amended. An up-to-date listing of Contracting States that have adopted Article **22** (1) as amended is maintained at WIPO's website at http://www.wipo.int/pct/en/texts/pdf/time_limits.pdf. For those few remaining Contracting States that have not adopted Article **22**(1) as amended, if no "Demand" for international preliminary examination has been filed within 19 months of the priority date, the applicant may be required to complete the requirements for entering the national stage within 20 months from the priority date of the international application in the national offices of those states. When entering the national stage following Chapter I, the applicant has the right to amend the application within the time limit set forth in PCT Rule **52.1**. After this time limit has expired (PCT Article **28** and PCT Rule **52**), each designated Office will make its own determination as to the patentability of the application based upon its own specific national or regional laws (PCT Article **27**(5)).

If the applicant desires to obtain the benefit of delaying the entry into the national stage until 30 months from the priority date in one or more countries where the 30 month time limit set forth in PCT Article **22**(1) as amended does not apply, a Demand for international preliminary examination must be filed with an appropriate International Preliminary Examining Authority within 19 months of the priority date. Those states in which the Chapter II procedure is desired must be "elected" in the Demand. For international applications filed on or after January 1, 2004, the applicant should file the demand with the competent International Preliminary Examining Authority (IPEA) before the expiration of the later of the following time limits: (A) three months from the date of transmittal to the applicant of the international search report and written opinion under PCT Rule **43*bis*.1**, or of the declaration referred to in PCT Article **17**(2)(a); or (B) 22 months from the priority date of the international application. However, applicant may still desire to file the demand by 19 months from the priority date for those countries that have not yet adopted PCT Article **22**(1) as amended.

The original Demand is forwarded to the International Bureau by the IPEA. The International Bureau then notifies the various elected Offices that the applicant has entered Chapter II and sends a copy of any amendments filed under PCT Article **19** and any statement explaining the amendments to the IPEA. See PCT Rule **62**. In applications filed on or after January 1, 2004, the International Bureau also sends the IPEA a copy of the written opinion established by the International Searching Authority unless the International Searching Authority is also acting as IPEA. See PCT Rule **62.1**(i).

VI. INTERNATIONAL PRELIMINARY EX- AMINING AUTHORITY (IPEA)

The International Preliminary Examining Authority (IPEA) normally starts the examination process when it is in possession of:

(A) the demand;

(B) the amount due;

(C) if the applicant is required to furnish a translation under **PCT Rule 55.2, that translation**;

(D) either the international search report or a notice of the declaration by the International Searching Authority (ISA) that no international search report will be established; and

(E) if the international application has a filing date on or after January 1, 2004, the written opinion established under **PCT Rule 43*bis*.1**.

However, for international applications having an international filing date on or after January 1, 2004, the IPEA shall not start the international preliminary examination before the expiration of the later of three months from the transmittal of the international search report (or declaration that no international search report will be established) and written opinion; or the expiration of 22 months from the priority date unless the applicant expressly requests an earlier start, with the exception of

the situations provided for in PCT Rule **69.1**(b)-(e).

The written opinion of the ISA is usually considered the first written opinion of the IPEA unless the IPEA has notified the International Bureau that written opinions established by specified International Searching Authorities shall not be considered a written opinion for this purpose. See PCT Rule **66.1*bis***. Also, the IPEA may, at its discretion issue further written opinions provided sufficient time is available. See PCT Rule **66.4**.

The IPEA establishes the international preliminary examination report (entitled "international preliminary report on patentability" for applications having an international filing date on or after January 1, 2004), which presents the examiner's final position as to whether each claim is "novel," involves "inventive step," and is "industrially applicable" by 28 months from the priority date. A copy of the international preliminary examination report is sent to the applicant and to the International Bureau. The International Bureau then communicates a copy of the international preliminary examination report to each elected Office.

The applicant must complete the requirements for entering the national stage by the expiration of 30 months from the priority date to avoid any question of withdrawal of the application as to that elected Office; however, some elected Offices provide a longer period to complete the requirements.

A listing of all national and regional offices, and the corresponding time limits for entering the national stage after PCT Chapter I and PCT Chapter II, may be found on WIPO's web site at: http://www.wipo.int/pct/en/index.html.

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Exhibit 7

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1893.03(c) The Priority Date, Priority Claim, and Priority Papers for a U.S. National Stage Application [R-6] - 1800 Patent Cooperation Treaty

1893.03(c) The Priority Date, Priority Claim, and Priority Papers for a U.S. National Stage Application [R-6]

A U.S. national stage application may be entitled to: (A) a right of priority under 35 U.S.C. **119**(a) and **365**(b) based on a prior foreign application or international application designating at least one country other than the United States; and (B) the benefit of an earlier filed U.S. national application or international application designating the United States pursuant to 35 U.S.C. **119**(e) or 35 U.S.C. **120** and **365**(c).

I. RIGHT OF PRIORITY UNDER 35 U.S.C. 119(a) and 365(b)

Pursuant to 35 U.S.C. **365**(b) a U.S. national stage application shall be entitled to a right of priority based on a prior foreign application or international application designating at least one country other than the United States in accordance with the conditions and requirements of 35 U.S.C. **119**(a) and the treaty and the PCT regulations. See in particular PCT Article **8** and PCT Rules **4.10** and ***26bis***. To obtain priority in the U.S. national stage application to such applications, the priority must have been timely claimed in the international stage of the international application. See 37 CFR **1.55**(a)(1)(ii). If priority was properly claimed in the international stage of the international application, the claim for priority is acknowledged >(subject to the paragraph below)< and the national stage application file is checked to see if the file contains a copy of the certified copy of the priority document submitted to the International Bureau.

>International applications filed on or after April 1, 2007 are subject to amended

PCT Rules permitting restoration of a right of priority. See MPEP § **1828.01**. Consequently, international applications filed on or after April 1, 2007 may claim priority to a foreign application filed more than 12 months before the filing date of the international application. While such priority claims are permitted in the international stage, the right of priority will not be effective in the U.S. national stage, as 35 U.S.C. **119**(a) does not permit a priority period that exceeds 12 months.<

If the priority claim in the national stage application is to an application, the priority of which was not claimed in the international stage of the international application, the claim for priority must be denied for failing to meet the requirements of the Patent Cooperation Treaty, specifically **PCT Rule 4.10**.

For a comparison with **35 U.S.C. 119(a)**-(d) priority claims in a national application filed under **35 U.S.C. 111(a),** see **MPEP § 1895.01**.

II. THE CERTIFIED COPY

The requirement in **PCT Rule 17** for a certified copy of the foreign priority application is normally fulfilled by applicant providing a certified copy to the receiving Office or to the International Bureau or by applicant requesting the receiving Office to prepare and transmit the priority document to the International Bureau if the receiving Office issued the priority document. Pursuant to PCT Rule **17.1**(a)-(b), applicant must submit the certified copy, or request the receiving Office to prepare and transmit the certified copy, within 16 months from the priority date. Where applicant has complied with PCT Rule **17**, the International Bureau will **>forward a copy of the certified priority document to each Designated Office that has requested such document with an indication that the priority document was submitted in compliance with the rule and the date the document was received by the International Bureau. This indication may be in the form of either a cover sheet attached to the copy of the priority document or a WIPO stamp on the face of the certified copy.< The U.S. Patent and Trademark Office, as a Designated Office, will normally request the International Bureau to furnish the copy of the certified priority document upon receipt of applicant's submission under 35 U.S.C. **371** to enter the U.S. national phase. The copy from the International Bureau is placed in the U.S. national stage file. The copy of the **>priority document received from the International Bureau with either of the indications above< is acceptable to establish that applicant has filed a certified copy of the priority document. The examiner should acknowledge in the next Office action that the copy of the certified copy of the foreign priority document has been received in the national stage application from the International Bureau.

**>On the following pages, note the examples of acceptable indications in the form of:

(A) a cover sheet indicating receipt by the International Bureau on 02 February 2006 and compliance with PCT Rule **17** in the "Remark" section; and

(B) <the stamp (box) in the upper right hand section indicating receipt by the International Bureau (WIPO) on 30 December 2002 and the stamped indication

"PRIORITY DOCUMENT SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)."

>

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/JP2005/023454

International filing date: 21 December 2005 (21.12.2005)

Document type: Certified copy of priority document

Document details: Country/Office: JP
Number: 2004-368955
Filing date: 21 December 2004 (21.12.2004)

Date of receipt at the International Bureau: 02 February 2006 (02.02.2006)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

日本国特許庁
JAPAN PATENT OFFICE

別紙添付の書類に記載されている事項は下記の出願書類に記載されている事項と同一であることを証明する。

This is to certify that the annexed is a true copy of the following application as filed with this Office.

出願年月日 Date of Application:	２００４年１２月２１日
出願番号 Application Number:	特願２００４－３６８９５５
パリ条約による外国への出願に用いる優先権の主張の基礎となる出願の国コードと出願番号 The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is	ＪＰ２００４－３６８９５５
出願人 Applicant(s):	エーザイ株式会社

２００６年　１月１８日

特許庁長官
Commissioner,
Japan Patent Office

中嶋　誠

【書類名】　特許願
【整理番号】　EP04SD1102
【あて先】　特許庁長官殿
【国際特許分類】　B01J 2/00
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【手数料の表示】
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　【物件名】　要約書 1
　【物件名】　図面 1
　【物件名】　特許請求の範囲 1

<

PCT/AU02/01658

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

Patent Office
Canberra

I, JONNE YABSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Complete specification in connection with Innovation Patent No. 2001100629 for a patent by WESTAFLEX (AUSTRALIA) PTY. LTD. as filed on 07 December 2001.

WITNESS my hand this
Nineteenth day of December 2002

J R Yabsley

JONNE YABSLEY
TEAM LEADER EXAMINATION
SUPPORT AND SALES

If the International Bureau is unable to forward a copy of the certified priority document to the U.S. Patent and Trademark Office because applicant failed to

comply with PCT Rule **17**(a)-(b), then applicant will have to provide a certified copy of the priority document >(or have the priority document furnished in accordance with 37 CFR **1.55**(d))< during the national stage to fulfill the requirement of **37 CFR 1.55(a)(2)**.

III. BENEFIT CLAIM UNDER 35 U.S.C. 119(e), OR 120 AND 365(c)

A national stage application may include a benefit claim under 35 U.S.C. **119**(e), or **120** and **365**(c) to a prior U.S. national application or under 35 U.S.C. **120** and **365** (c) to a prior international application designating the U.S. The conditions for according benefit under **35 U.S.C. 120** are as described in **MPEP § 201.07**, **§ 201.08**, and **§ 201.11** and are similar regardless of whether the U.S. national application is a national stage application submitted under **35 U.S.C. 371** or a national application filed under **35 U.S.C. 111(a).**

The conditions for according benefit under 35 U.S.C. **119**(e) are also similar for national stage applications and applications filed under 35 U.S.C. **111**(a), and the conditions are described in MPEP § **201.11**.

In order for a national stage application (of international application "X") to obtain benefit under 35 U.S.C. **119(e)** of a prior U.S. provisional application, the national stage application must comply with the requirements set forth in 37 CFR **1.78(a)(4)** through 37 CFR **1.78(a)(6)**. Public Law 106-113 amended 35 U.S.C. **119(e)** to eliminate the copendency requirement for a nonprovisional application claiming benefit of a provisional application. 35 U.S.C. **119(e)(2)** as amended became effective on November 29, 1999 and applies to provisional applications filed on or after June 8, 1995. 37 CFR **1.78(a)(4)** requires that the prior provisional application must be entitled to a filing date as set forth in 37 CFR **1.53(c)**, and the basic filing fee set forth in 37 CFR **1.16(d)** must be paid on the provisional application within the time period set forth in 37 CFR **1.53(g)**. Additionally, the provisional application must name as an inventor at least one inventor named in the later filed international application "X" and disclose the named inventor's invention claimed in at least one claim of the national stage application in the manner provided by the first paragraph of 35 U.S.C. **112**. The national stage application must contain a reference to the provisional application (either in an application data sheet (37 CFR **1.76**) or in the first sentence(s) of the specification), identifying it as a provisional application, and including the provisional application number (series code and serial number). The required reference to the earlier provisional application must be submitted within the time period provided by 37 CFR **1.78(a)(5)(ii)**. This time period is not extendable. However, if the entire delay, between the date the claim was due under 37 CFR **1.78**(a)(5)(ii) and the date the claim was filed, was unintentional, a petition under 37 CFR **1.78**(a)(6) may be filed to accept the delayed claim. If the provisional application was filed in a language other than English, an English-language translation of the non-English language provisional application and a statement that the translation is accurate will be required. See MPEP § **201.11**, subsection VI. If the translation and statement that the translation is accurate were not filed in the provisional application or in the later-filed national stage application before November 25, 2005, applicant will be notified and given a period of time within which to file an English-language translation and a statement that the translation is accurate in the provisional application, and a reply in the national stage application

that the translation and statement were filed in the provisional application. Failure to timely reply to such a notice will result in abandonment of the national stage application. See 37 CFR **1.78(a)(5)(iv)**.

In order for a national stage application (of international application "X") to obtain benefit under 35 U.S.C. **120** and **365(c)** of a prior filed copending nonprovisional application or prior filed copending international application designating the United States of America, the national stage application must comply with the requirements set forth in 37 CFR 1.78(a)(1) through 37 CFR **1.78(a)(3)**. The prior nonprovisional application or international application must name as an inventor at least one inventor named in the later filed international application "X" and disclose the named inventor's invention claimed in at least one claim of the national stage application in the manner provided by the first paragraph of 35 U.S.C. **112**. The national stage application must contain a reference to the prior nonprovisional or international application (either in an application data sheet (37 CFR **1.76**) or in the first sentence(s) of the specification), identifying it by application number (series code and serial number) or international application number and international filing date and indicating the relationship of the applications. The required reference to the earlier filed application must be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. **371**(b) or (f) or sixteen months from the filing date of the prior-filed application. This time period is not extendable and failure to timely submit the required reference to the earlier application will be considered a waiver of any benefit under 35 U.S.C. **120**, **121**, or **365**(c) to such prior-filed application. See 37 CFR **1.78**(a)(2)(ii). However, if the entire delay, between the date the claim was due under 37 CFR **1.78**(a)(2)(ii) and the date the claim was filed, was unintentional, a petition under 37 CFR 1.78(a)(3) may be filed to accept the delayed claim.

A prior filed nonprovisional application is copending with the national stage application if the prior U.S. national application was pending on the international filing date of the national stage application.

A *>prior-filed< international application designating the United States of America is copending with the national stage application if the prior international application was not abandoned or withdrawn >, either generally or as to the United States,< on the international filing date of **>the national stage application.<

Note: a national stage application submitted under 35 U.S.C. **371** may not claim benefit of the filing date of the international application of which it is the national stage since its filing date is the **>international filing date of the< international application. See also **MPEP § 1893.03(b)**. Stated differently, since the international application is not an earlier application (it has the same filing date as the national stage), a benefit claim under 35 U.S.C. **120** in the national stage to the international application is inappropriate and may result in the submission being treated as an application filed under 35 U.S.C. **111**(a). See MPEP § **1893.03(a)**. Accordingly, it is not necessary for the applicant to amend the first sentence(s) of the specification to reference the international application number that was used to identify the application during international processing of the application by the international authorities prior to commencement of the national stage.

For a comparison with **35 U.S.C. 120** benefit claims in a national application filed under **35 U.S.C. 111(a)**, see **MPEP § 1895**.

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Exhibit 8

201.13 Right of Priority of Foreign Application [R-3] - 200 Types, Cross-Noting, and Status of Application

201.13 Right of Priority of Foreign Application [R-3]

Under certain conditions and on fulfilling certain requirements, an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country, to overcome an intervening reference or for similar purposes. The conditions are specified in **35 U.S.C. 119(a)**-(d) and (f)>, and **37 CFR 1.55**<.

35 U.S.C. 119 Benefit of earlier filing date; right of priority.

(a) An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; but no patent shall be granted on any application for patent for an invention which had been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing.

(b)

(1) No application for patent shall be entitled to this right of priority unless a claim is filed in the Patent and Trademark Office, identifying the foreign application by specifying the application number on that foreign application, the intellectual property authority or country in or for which the application was filed, and the date of filing the application, at such time during the pendency of the application as required by the Director.

(2) The Director may consider the failure of the applicant to file a timely claim for priority as a waiver of any such claim. The Director may establish procedures,

including the payment of a surcharge, to accept an unintentionally delayed claim under this section.

(3) The Director may require a certified copy of the original foreign application, specification, and drawings upon which it is based, a translation if not in the English language, and such other information as the Director considers necessary. Any such certification shall be made by the foreign intellectual property authority in which the foreign application was filed and show the date of the application and of the filing of the specification and other papers.

(c) In like manner and subject to the same conditions and requirements, the right provided in this section may be based upon a subsequent regularly filed application in the same foreign country instead of the first filed foreign application, provided that any foreign application filed prior to such subsequent application has been withdrawn, abandoned, or otherwise disposed of, without having been laid open to public inspection and without leaving any rights outstanding, and has not served, nor thereafter shall serve, as a basis for claiming a right of priority.

(d) Applications for inventors' certificates filed in a foreign country in which applicants have a right to apply, at their discretion, either for a patent or for an inventor"s certificate shall be treated in this country in the same manner and have the same effect for purpose of the right of priority under this section as applications for patents, subject to the same conditions and requirements of this section as apply to applications for patents, provided such applicants are entitled to the benefits of the Stockholm Revision of the Paris Convention at the time of such filing.

*****

(f) Applications for plant breeder's rights filed in a WTO member country (or in a foreign UPOV Contracting Party) shall have the same effect for the purpose of the right of priority under subsections (a) through (c) of this section as applications for patents, subject to the same conditions and requirements of this section as apply to applications for patents.

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37 CFR 1.55 Claim for foreign priority.

(a) An applicant in a nonprovisional application may claim the benefit of the filing date of one or more prior foreign applications under the conditions specified in 35 U.S.C. **119(a)** through **(d) and (f)**, **172**, and **365(a) and (b)**.

(1)

(i) In an original application filed under 35 U.S.C. **111(a)**, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the

filing date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority is claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time periods in this paragraph do not apply in an application under 35 U.S.C. **111**(a) if the application is:

(A) A design application; or

(B) An application filed before November 29, 2000.

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. **371**, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT.

(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. **119(b)** or PCT Rule **17** must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § **1.17(i)**, but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. **255** and § **1.323**

**>

(3) The Office may require that the claim for priority and the certified copy of the foreign application be filed earlier than provided in paragraphs (a)(1) or (a)(2) of this section:

(i) When the application becomes involved in an interference (see § **41.202** of this title),

(ii) When necessary to overcome the date of a reference relied upon by the examiner, or

(iii) When deemed necessary by the examiner.

(4)

(i) An English language translation of a non-English language foreign application is not required except:

(A) When the application is involved in an interference (see § **41.202** of this title),

(B) When necessary to overcome the date of a reference relied upon by the examiner, or

(C) When specifically required by the examiner.

(ii) If an English language translation is required, it must be filed together with a statement that the translation of the certified copy is accurate.<

*****

The period of 12 months specified in this section is 6 months in the case of designs, **35 U.S.C. 172**. See **MPEP § 1504.10**.

The conditions, for benefit of the filing date of a prior application filed in a foreign country, may be listed as follows:

(A) The foreign application must be one filed in "a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States or in a WTO member country."

(B) The foreign application must have been filed by the same applicant (inventor) as the applicant in the United States, or by his or her legal representatives or assigns.

(C) The application, or its earliest parent United States application under **35 U.S.C. 120**, must have been filed within 12 months from the date of the earliest foreign filing in a "recognized" country as explained below.

(D) The foreign application must be for the same invention as the application in the United States.

(E) For an original application filed under **35 U.S.C. 111(a)** (other than a design application) on or after November 29, 2000, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. This time period is not extendable.

(F) For applications that entered the national stage from an international application filed on or after November 29, 2000, after compliance with **35 U.S.C. 371**, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT Article and Regulations.

(G) In the case where the basis of the claim is an application for an inventor"s certificate, the requirements of **37 CFR 1.55(b)** must also be met.

Applicant may be informed of possible priority rights under **35 U.S.C. 119(a)**-(d) >and (f)< by using the wording of form paragraph 2.18.

¶ 2.18 Right of Priority Under 35 U.S.C. 119(a)-(d) and (f)

Applicant is advised of possible benefits under **35 U.S.C. 119(a)**-(d) and (f), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country.

I. RECOGNIZED COUNTRIES OF FOREIGN FILING

The right to rely on a foreign application is known as the right of priority in international patent law and this phrase has been adopted in the U.S. statute. The right of priority originated in a multilateral treaty of 1883, to which the United States adhered in 1887, known as the Paris Convention for the Protection of Industrial Property (Paris Convention). The treaty is administered by the World Intellectual Property Organization (WIPO) at Geneva, Switzerland. This treaty has been revised several times, the latest revision in effect being written in Stockholm in July 1967 (copy at Appendix P of this Manual). Articles 13-30 of the Stockholm Revision became effective on September 5, 1970. Articles 1-12 of the Stockholm Revision became effective on August 25, 1973. One of the many provisions of the treaty requires each of the adhering countries to accord the right of priority to the nationals of the other countries and the first United States statute relating to this subject was enacted to carry out this obligation. There is another treaty between the United States and some Latin American countries which also provides for the right of priority. A foreign country may also provide for this right by reciprocal legislation.

The United States and Taiwan signed an agreement on priority for patent and trademark applications on April 10, 1996, and Taiwan is now a country for which the right of priority is recognized in the United States. Applicants seeking patent protection in the United States may avail themselves of the right of priority based on patent applications filed in Taiwan, on or after April 10, 1996.

An application for patent filed in the United States on or after January 1, 1996, by any person who has, or whose legal representatives or assigns have, previously filed an application for patent in Thailand shall have the benefit of the filing date in Thailand in accordance with **35 U.S.C. 119** and 172.

NOTE: Following is a list of countries with respect to which the right of priority referred to in **35 U.S.C. 119(a)**-(d) has been recognized. The letter "I" following the name of the country indicates that the basis for priority in the case of these countries is the Paris Convention for the Protection of Industrial Property (613 O.G. 23, 53 Stat. 1748). The letter "P" after the name of the country indicates the basis for priority of these countries is the Inter-American Convention relating to Inventions, Patents, Designs, and Industrial Models, signed at Buenos Aires, August 20, 1910 (207 O.G. 935, 38 Stat. 1811). The letter "L" following the name of the country indicates the basis for priority is reciprocal legislation in the particular country. The letter "W" following the name of the country indicates the basis for priority is membership in the World Trade Organization (WTO). See **35 U.S.C. 119 (a)**. The letter "W°" indicates that the country became a WTO member after January 1, 1996. See http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm for a current list of WTO member countries along with their dates of membership. Applications for plant breeder's rights filed in WTO member countries and foreign UPOV contracting parties may be relied upon for priority pursuant to **35 U.S.C. 119(f)** and **MPEP Chapter 1600**.

Albania (I, W°),

Algeria (I),

Angola (W°),

>Andorra (I),<

Antigua and Barbuda (I, W),

Argentina (I, W),

Armenia (I>, W°<),

Australia (I, W),

Austria (I, W),

Azerbaijan (I),

Bahamas (I),

Bahrain (I, W),

Bangladesh (I, W),

Barbados (I, W),

Belarus (I),

Belgium (I, W),

Belize (I, W),

Benin (I, W°),

Bhutan (I),

Bolivia (I, P, W),

Bosnia and Herzegovina (I),

Botswana (I, W),

Brazil (I, P, W),

Brunei Darussalam (W),

Bulgaria (I, W°),

Burkina Faso (I, W),

Burundi (I, W),

Cambodia (I>, W°<),

Cameroon (I, W),

Canada (I, W),

Central African Republic (I, W),

Chad (I, W°),

Chile (I, W),

China (I, W°),

Colombia (I, W),

>Comoros (I),<

Congo (I, W°),

Costa Rica (I, P, W),

Cote d'Ivoire (I, W),

Croatia (I, W°),

Cuba (I, P, W),

Cyprus (I, W),

Czech Republic (I, W),

Democratic People's Republic of Korea (I),

Democratic Republic of the Congo (I, W°),

Denmark (I, W),

Djibouti (I, W),

Dominica (I, W),

Dominican Republic (I, P, W),

Ecuador (I, P, W°),

Egypt (I, W),

El Salvador (I, W),

Equatorial Guinea (I),

Estonia (I, W°),

European Community (W),

Fiji (W°),

Finland (I, W),

France (I, W),

Gabon (I, W),

Gambia (I, W°),

Georgia (I, W°),

Germany (I, W),

Ghana (I, W),

Greece (I, W),

Grenada (I, W°),

Guatemala (I, P, W),

Guinea (I, W),

Guinea-Bissau (I , W),

Guyana (I, W),

Haiti (I, P, W°),

Holy See (I),

Honduras (I, P, W),

Hong Kong Special Administrative Region of China (I, W),

Hungary (I, W),

Iceland (I, W),

India (I, W),

Indonesia (I, W),

Iran (Islamic Republic of) (I),

Iraq (I),

Ireland (I, W),

Israel (I, W),

Italy (I, W),

Jamaica (I, W),

Japan (I, W),

Jordan (I, W°),

Kazakstan (I),

Kenya (I, W),

Kuwait (W),

Kyrgyzstan (I, W°),

Lao People's Democratic Republic (I),

Latvia (I, W°),

Lebanon (I),

Lesotho (I, W),

Liberia (I),

Libya (I),

Libyan Arab Jamahiriya (I),

Liechtenstein (I, W),

Lithuania (I, W°),

Luxembourg (I, W),

Macau Special Administrative Region of China (I, W),

Madagascar (I, W),

Malawi (I, W),

Malaysia (I, W),

Maldives (W),

Mali (I, W),

Malta (I, W),

Mauritania (I, W),

Mauritius (I, W),

Mexico (I, W),

Monaco (I),

Mongolia (I, W°),

Morocco (I, W),

Mozambique (I, W),

Myanmar (W),

Namibia (I, W),

Nepal (I>, W°<),

Netherlands (I, W,),

New Zealand (I, W),

Nicaragua (I, P, W),

Niger (I, W°),

Nigeria (I, W),

Norway (I, W),

Oman (I, PW°),

Pakistan (>I,< W),

Panama (I, W°),

Papua New Guinea (I, W°),

Paraguay (I, P, W),

Peru (I, W),

Philippines (I, W),

Poland (I, W),

Portugal (I, W),

Qatar (I, W°),

Republic of Korea (I, W),

Republic of Moldova (I, W°),

Romania (I, W),

Russian Federation (I),

Rwanda (I, W°),

Saint Kitts and Nevis (I, W°),

Saint Lucia (I, W),

Saint Vincent and the Grenadines (I, W),

San Marino (I),

Sao Tome and Principe (I),

Saudi Arabia (I)

Senegal (I, W),

Serbia and Montenegro (I)

Seychelles (I)

Sierra Leone (I, W),

Singapore (I, W),

Slovakia (I, W),

Slovenia (I, W),

Solomon Islands (W°),

South Africa (I, W),

Spain (I, W),

Sri Lanka (I, W),

Sudan (I),

Suriname (I, W),

Swaziland (I, W),

Sweden (I, W),

Switzerland (I, W),

Syrian Arab Republic (I),

Taiwan>, Province of China (Chinese Taipei)< (L, W°),

Tajikistan (I),

Tanzania, United Republic of (I, W),

Thailand (L, W),

The former Yugoslav Republic of Macedonia (I, W°),

Togo (I, W),

Tonga (I),

Trinidad and Tobago (I, W),

Tunisia (I, W),

Turkey (I, W),

Turkmenistan (I),

Uganda (I, W),

Ukraine (I),

United Arab Emirates (I, W°),

United Kingdom (I, W),

Uruguay (I, P, W),

Uzbekistan (I),

Venezuela (I, W),

Viet Nam (I),

Zambia (I, W),

Zimbabwe (I, W).

Sixteen African Countries have joined together to create a common patent office and to promulgate a common law for the protection of inventions, trademarks, and designs. The common patent office is called "Organisation Africain de la Propriete Intellectuelle" (OAPI) and is located in Yaounde, Cameroon. The English title is "African Intellectual Property Organization." The member countries using the OAPI Patent Office are Benin, Cameroon, Central African Republic, Chad, Congo, Gabon, Cote d'Ivoire, Mauritania, Niger, Senegal, Republic of Togo, Burkina Faso>,< Guinea, Guinea-Bissau, Mali and Equatorial Guinea. Since all these countries adhere to the Paris Convention for the Protection of Industrial Property, priority under **35 U.S.C. 119(a)**-(d) may be claimed of an application filed in the OAPI Patent Office.

If any applicant asserts the benefit of the filing date of an application filed in a country not on this list, the examiner should contact the Office of International Relations to determine if there has been any change in the status of that country. It should be noted that the right is based on the *country* of the foreign filing and not upon the citizenship of the applicant.

II. RIGHT OF PRIORITY (35 U.S.C. 119(a)-(d) AND 365) BASED ON A FOREIGN APPLICATION FILED UNDER A BILATERAL OR MULTILATERAL TREATY

Under Article 4A of the Paris Convention for the Protection of Industrial Property a right of priority may be based either on an application filed under the national law of a foreign country adhering to the Convention or on a foreign application filed under a bilateral or multilateral treaty concluded between two or more such countries. Examples of such treaties are The Hague Agreement Concerning the International Deposit of Industrial Designs, the Benelux Designs Convention, and the Libreville Agreement of September 13, 1962, relating to the creation of an African Intellectual Property Office. The Convention on the Grant of European Patents, the Patent Cooperation Treaty (**MPEP § 201.13(b)**), the Office for Harmonization in the Internal Market (OHIM), and the Community Plant Variety Office (CPVO) are further examples of such treaties.

A. The Priority Claim

A priority claim need not be in any special form and may be a statement signed by a registered attorney or agent. A priority claim can be made on filing: (A) by including a copy of an unexecuted or executed oath or declaration specifying a foreign priority claim (see **37 CFR 1.63(c)(2)**); or (B) by submitting an application data sheet specifying a foreign priority claim (see **37 CFR 1.76)**.

In claiming priority of a foreign application previously filed under such a treaty, certain information must be supplied to the U.S. Patent and Trademark Office. In addition to the application number and the date of the filing of the application, the following information is required: (A) the name of the treaty under which the application was filed; and (B) the name and location of the national or intergovernmental authority which received such application.

B. Certification of the Priority Papers

35 U.S.C. 119(b)(3) authorizes the Office to require the applicant to furnish a certified copy of priority papers. Applicants are required to submit the certified copy of the foreign application specified in **35 U.S.C. 119(b)** or **PCT Rule 17** before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in **37 CFR 1.17(i)**, but the patent will not include the priority claim unless corrected by a certificate of correction under **35 U.S.C. 255** and **37 CFR 1.323**. See **37 CFR 1.55(a)(2)**. Certification by the authority empowered under a bilateral or multilateral treaty to receive applications which give rise to a right of priority under Article 4A(2) of the Paris Convention will be deemed to satisfy the certification requirement.

C. Identity of Inventors

The inventors of the U.S. nonprovisional application and of the foreign application must be the same, for a right of priority does not exist in the case of an application of inventor A in the foreign country and inventor B in the United States, even though the two applications may be owned by the same party. However, the application in the foreign country may have been filed by the assignee, or by the legal representative or agent of the inventor which is permitted in some foreign countries, rather than by the inventor himself, but in such cases the name of the inventor is usually given in the foreign application on a paper filed therein. An indication of the identity of inventors made in the oath or declaration accompanying the U.S. nonprovisional application by identifying the foreign application and stating that the foreign application had been filed by the assignee, or the legal representative, or agent, of the inventor, or on behalf of the inventor, as the case may be, is acceptable. Joint inventors A and B in a nonprovisional application filed in the United States Patent and Trademark Office may properly claim the benefit of an application filed in a foreign country by A and another application filed in a foreign country by B, i.e., A and B may each claim the benefit of their foreign filed applications. See **MPEP § 605.07**.

D. Time for Filing U.S. Nonprovisional Application

The United States nonprovisional application, or its earliest parent nonprovisional application under **35 U.S.C. 120**, must have been filed within 12 months of the earliest foreign filing. In computing this 12 months, the first day is not counted; thus, if an application was filed in Canada on January 3, 1983, the U.S. nonprovisional application may be filed on January 3, 1984. The Convention specifies in Article 4C (2) that "the day of filing is not counted in this period." (This is the usual method of computing periods, for example a 6-month period for reply to an Office action dated

January 2 does not expire on July 1, but the reply may be made on July 2.) If the last day of the 12 months is a Saturday, Sunday, or Federal holiday within the District of Columbia, the U.S. nonprovisional application is in time if filed on the next succeeding business day; thus, if the foreign application was filed on September 4, 1981, the U.S. nonprovisional application is in time if filed on September 7, 1982, since September 4, 1982, was a Saturday and September 5, 1982 was a Sunday and September 6, 1982 was a Federal holiday. Since January 1, 1953, the Office has not received applications on Saturdays and, in view of **35 U.S.C. 21**, and the Convention which provides "if the last day of the period is an official holiday, or a day on which the Office is not open for the filing of applications in the country where protection is claimed, the period shall be extended until the first following working day" (Article 4C(3)), if the 12 months expires on Saturday, the U.S. application may be filed on the following Monday. Note *Ex parte Olah*, 131 USPQ 41 (Bd. App. 1960). See, e.g., *Dubost v. U.S. Patent and Trademark Office,* 777 F.2d 1561, 1562, 227 USPQ 977, 977 (Fed. Cir. 1985).

E. Filing of Papers During Unscheduled Closings of the U.S. Patent and Trademark Office

37 CFR 1.9(h) provides that the definition of "Federal holiday within the District of Columbia" includes an official closing of the Office. When the entire U.S. Patent and Trademark Office is officially closed for business for an entire day, for reasons due to adverse weather or other causes, the Office will consider each such day a "Federal holiday within the District of Columbia" under **35 U.S.C. 21**. Any action or fee due on such a day may be taken, or fee paid, on the next succeeding business day the Office is open. In addition, **37 CFR 1.6(a)**(1) provides "[t]he U.S. Patent and Trademark Office is not open for the filing of correspondence on any day that is a Saturday, Sunday or Federal holiday within the District of Columbia" to clarify that any day that is a Saturday, Sunday or Federal holiday within the District of Columbia is a day that the U.S. Patent and Trademark Office is not open for the filing of applications within the meaning of Article 4C(3) of the Paris Convention. Note further that in accordance with **37 CFR 1.6(a)**(2), even when the Office is not open for the filing of correspondence on any day that is a Saturday, Sunday or Federal holiday within the District of Columbia, correspondence deposited as Express Mail with the USPS in accordance with **37 CFR 1.10** will be considered filed on the date of its deposit, regardless of whether that date is a Saturday, Sunday or Federal holiday within the District of Columbia (under **35 U.S.C. 21(b)** or **37 CFR 1.7**).

When the U.S. Patent and Trademark Office is open for business during any part of a business day between 8:30 a.m. and 5:00 p.m., papers are due on that day even though the Office may be officially closed for some period of time during the business day because of an unscheduled event. The procedures of **37 CFR 1.10** may be used for filing applications.

Information regarding whether or not the Office is officially closed on any particular day may be obtained by calling **>1-800-PTO-9199 or (571) 272-1000<.

F. First Foreign Application

The 12 months is from earliest foreign filing except as provided in 35 U.S.C 119(c). If an inventor has filed an application in France on January 4, 1982, and an identical application in the United Kingdom on March 3, 1982, and then files in the United States on February 2, 1983, the inventor is not entitled to the right of priority at all; the inventor would not be entitled to the benefit of the date of the French application since this application was filed more than twelve months before the U.S. application, and the inventor would not be entitled to the benefit of the date of the United Kingdom application since this application is not the first one filed. *Ahrens v. Gray*, 1931 C.D. 9, 402 O.G. 261 (Bd. App. 1929). If the first foreign application was filed in a country which is not recognized with respect to the right of priority, it is disregarded for this purpose.

Public Law 87-333 modified **35 U.S.C. 119(c)** to extend the right of priority to "subsequent" foreign applications if one earlier filed had been withdrawn, abandoned, or otherwise disposed of, under certain conditions.

The United Kingdom and a few other countries have a system of "post-dating" whereby the filing date of an application is changed to a later date. This "post-dating" of the filing date of the application does not affect the status of the application with respect to the right of priority; if the original filing date is more than one year prior to the U.S. filing no right of priority can be based upon the application. See *In re Clamp,* 151 USPQ 423 (Comm'r Pat. 1966).

If an applicant has filed two foreign applications in recognized countries, one outside the year and one within the year, and the later application discloses additional subject matter, a claim in the U.S. application specifically limited to the additional disclosure would be entitled to the date of the second foreign application since this would be the first foreign application for that subject matter.

G. Incorporation by Reference

>An applicant may incorporate by reference the foreign priority application by including, in the U.S. application-as-filed, an explicit statement that such specifically enumerated foreign priority application or applications are "hereby incorporated by reference." The statement must appear in the specification. See 37 CFR **1.57(b) and MPEP § **608.01(p)**. For U.S. applications filed prior to September 21, 2004, the incorporation by reference statement may appear in the transmittal letter or in the specification. The inclusion of this statement of incorporation by reference of the foreign priority application will permit an applicant to amend the U.S. application to include subject matter from the foreign priority application(s), without raising the issue of new matter. Thus, the incorporation by reference statement can be relied upon to permit the entering of a portion of the foreign priority application into the U.S. application when a portion of the foreign priority application has been inadvertently omitted from the U.S. application, or to permit the correction of translation error in the U.S. application where the foreign priority application is in a non-English language.

For U.S. applications filed on or after September 21, 2004, a claim under 37 CFR **1.55** for priority of a prior-filed foreign application that was present on the filing date of the U.S. application is considered an incorporation by reference of the prior-filed

foreign priority application as to inadvertently omitted material, subject to the conditions and requirements of 37 CFR **1.57**(a). The purpose of 37 CFR **1.57**(a) is to provide a safeguard for applicants when all or a portion of the specification and/or drawing(s) is (are) inadvertently omitted from an application. For U.S. applications filed on or after September 21, 2004, applicants are encouraged to provide an explicit incorporation by reference statement to the prior-filed foreign priority application(s) for which priority is claimed under 37 CFR **1.55** if applicants do not wish the incorporation by reference to be limited to inadvertently omitted material pursuant to 37 CFR **1.57**(a). See 37 CFR **1.57**(b) and MPEP § **608.01(p)** for discussion regarding explicit incorporation by reference.<

III. EFFECT OF RIGHT OF PRIORITY

The right to rely on the foreign filing extends to overcoming the effects of intervening references or uses, but there are certain restrictions. For example, the 1 year bar of **35 U.S.C. 102(b)** dates from the U.S. filing date and not from the foreign filing date; thus if an invention was described in a printed publication, or was in public use in this country, in November 1981, a foreign application filed in January 1982, and a U.S. application filed in December 1982, granting a patent on the U.S. application is barred by the printed publication or public use occurring more than one year prior to its actual filing in the United States.

The right of priority can be based upon an application in a foreign country for a so-called "utility model," called Gebrauchsmuster in Germany.

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Exhibit 9

§ 1.55 Claim for foreign priority. - Appendix R Patent Rules

§ 1.55 Claim for foreign priority.

(a) An applicant in a nonprovisional application may claim the benefit of the filing date of one or more prior foreign applications under the conditions specified in 35 U.S.C. **119(a)** through **(d) and (f)**, **172**, and **365(a) and (b)**.

(1)

(i) In an original application filed under 35 U.S.C. **111(a)**, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority is claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time periods in this paragraph do not apply in an application under 35 U.S.C. **111**(a) if the application is:

(A) A design application; or

(B) An application filed before November 29, 2000.

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. **371**, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT.

(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. **119(b)** or PCT Rule **17** must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § **1.17(i)**, but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. **255** and § **1.323**

(3) The Office may require that the claim for priority and the certified copy of the

foreign application be filed earlier than provided in paragraphs (a)(1) or (a)(2) of this section:

(i) When the application becomes involved in an interference (see § **41.202** of this title),

(ii) When necessary to overcome the date of a reference relied upon by the examiner, or

(iii) When deemed necessary by the examiner.

(4)

(i) An English language translation of a non-English language foreign application is not required except:

(A) When the application is involved in an interference (see § **41.202** of this title),

(B) When necessary to overcome the date of a reference relied upon by the examiner, or

(C) When specifically required by the examiner.

(ii) If an English language translation is required, it must be filed together with a statement that the translation of the certified copy is accurate.

(b) An applicant in a nonprovisional application may under certain circumstances claim priority on the basis of one or more applications for an inventor's certificate in a country granting both inventor's certificates and patents. To claim the right of priority on the basis of an application for an inventor's certificate in such a country under **35 U.S.C. 119**(d), the applicant when submitting a claim for such right as specified in paragraph (a) of this section, shall include an affidavit or declaration. The affidavit or declaration must include a specific statement that, upon an investigation, he or she is satisfied that to the best of his or her knowledge, the applicant, when filing the application for the inventor's certificate, had the option to file an application for either a patent or an inventor's certificate as to the subject matter of the identified claim or claims forming the basis for the claim of priority.

(c) Unless such claim is accepted in accordance with the provisions of this paragraph, any claim for priority under **35 U.S.C. 119(a)-(d)** or **365(a)** not presented within the time period provided by paragraph (a) of this section is considered to have been waived. If a claim for priority under **35 U.S.C. 119(a)-(d)** or **365(a)** is presented after the time period provided by paragraph (a) of this section, the claim may be accepted if the claim identifying the prior foreign application by specifying its application number, country (or intellectual property authority), and the day, month, and year of its filing was unintentionally delayed. A petition to accept a delayed claim for priority under **35 U.S.C. 119(a)-(d)** or **365(a)** must be accompanied by:

(1) The claim under 35 U.S.C. **119**(a)-(d) or **365**(a) and this section to the prior

foreign application, unless previously submitted;

(2) The surcharge set forth in **§ 1.17(t)**; and

(3) A statement that the entire delay between the date the claim was due under paragraph (a)(1) of this section and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional.

(d)

(1) The requirement in this section for the certified copy of the foreign application will be considered satisfied if:

(i) The applicant files a request, in a separate document, that the Office obtain a copy of the foreign application from a foreign intellectual property office participating with the Office in a bilateral or multilateral priority document exchange agreement (participating foreign intellectual property office (see § **1.14** (h)(1));

(ii) The foreign application is identified in the oath or declaration (Sec. 1.63(c)) or an application data sheet (§ **1.76** (a)(6)); and

(iii) The copy of the foreign application is received by the Office within the period set forth in paragraph (a) of this section. Such a request should be made within the later of four months from the filing date of the application or sixteen months from the filing date of the foreign application.

(2) If the foreign application was filed at a foreign intellectual property office that is not participating with the Office in a priority document exchange agreement, but a copy of the foreign application was filed in an application subsequently filed in a participating foreign intellectual property office, the request under paragraph (d)(1)(i) of this section must identify the participating foreign intellectual property office and the application number of the subsequent application in which a copy of the foreign application was filed.

[para. (b), 47 FR 41275, Sept. 17, 1982, effective Oct. 1 1982; 48 FR 2710, Jan. 20, 1983, effective Feb. 27, 1983; para. (b), 49 FR 554, Jan. 4, 1984, effective Apr. 1, 1984; para. (a), 49 FR 48416, Dec. 12, 1984, effective Feb. 11, 1985; para. (a), 54 FR 6893, Feb. 15, 1989, effective Apr. 17, 1989; para. (a) revised, 54 FR 9432, March 7, 1989, effective Apr. 17, 1989; para. (a), 54 FR 47518, Nov. 15, 1989, effective Jan. 16, 1990; para. (a) revised, 58 FR 54504, Oct. 22, 1993, effective Jan. 3, 1994; revised, 60 FR 20195, Apr.25, 1995, effective June 8, 1995; para. (a) revised, 62 FR 53131, Oct. 10, 1997, effective Dec. 1, 1997; para. (a) revised, 65 FR 54604, Sept. 8, 2000, effective Nov. 7, 2000; para. (a) revised and para. (c) added, 65 FR 57024, Sept. 20, 2000, effective Nov. 29, 2000; paras. (a) and (c) corrected, 65 FR 66502, Nov. 6, 2000, effective Nov. 29, 2000; paras.(a)(1) and (c) revised, 66 FR 67087, Dec. 28, 2001, effective Dec. 28, 2001; para. (c)(3) revised, 68 FR 14332, Mar. 25, 2003, effective May 1, 2003; paras. (a)(3) and (a)(4) revised, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004; para. (d) added, 72 FR 1664, Jan. 16, 2007, effective Jan. 16, 2007]

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